

# NTP Historical Controls Report

By Route and Vehicle

**MICE** 

June 2013

# REPORT DESCRIPTION

This report shows the tumor rates of control group animals from selected studies. The studies used are shown on the Study Summary page.

This report is broken up into sections based on the route and vehicle used to deliver the chemical. The Table of Contents on Page 3 shows the different Route/Vehicle combinations. To see the data from all routes and vehicles combined into one set, you must run the "All Routes" report.

The individual tumor rates shown on the data pages of the report relate to the Study Summary page as follows: the tumor rates are shown in the same order as the Study Summary page, except that they are grouped horizontally in sets of three, with the males in the first set of three and the females in the second set. For example if the study summary showed the studies like this:

Male
M1
M2
M3
M4
M5
Female
Female F1
F1
F1 F2

the data would be shown as:

	Male		Female					
M1	M2	M3	F1	F2	F3			
M4	M5		F4	F5				

Directly beneath the individual tumor rates on the data pages are the overall totals for that tumor/site combination. This includes the total tumors/animals, the overall mean (in parentheses), the mean of the study means, and the standard deviation of the study means.

Studies with no control animals of a particular gender are listed on the summary page with the Number of Animals shown as zero and the Start Date and Length of Study shown as "N/A". On the data pages there are blank spaces where tumor rates for these studies would normally be found, so that the male and female rates for the remaining studies can be easily compared.

# **Table of Contents**

Route	Vehicle	Page Number
GAVAGE	CORN OIL	4
GAVAGE	METHYLCELLULOSE	52
GAVAGE	WATER	93
INHALATION	AIR	134
ORAL	WATER	182
SKIN	ACETONE	223
SKIN	ETHANOL	264

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Page: 4

Report Date: 06/05/2013

Route: GAVAGE Vehicle: CORN OIL

# **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Columbus Laboratory	059903104	03/17/05	726	50(1)	34(687)	54.6	Ginkgo biloba extract
Battelle Columbus Laboratory	052000604	04/03/07	730	50(1)	26(663)	55.6	Indole-3-carbinol
Battelle Columbus Laboratory	052000706	08/24/04	730	50(1)	34(689)	56.4	Kava kava extract
Battelle Columbus Laboratory	052010704	10/26/04	730	50(1)	34(665)	55.7	N,N-Dimethyl-p-toluidine
Battelle Columbus Laboratory	052032004	08/07/07	730	50(1)	33(687)	55.8	Tetrabromobisphenol A
					Female		
Battelle Columbus Laboratory	059903104	03/18/05	727	50(5)	31(628)	64.5	Ginkgo biloba extract
Battelle Columbus Laboratory	052000604	04/02/07	729	50(5)	33(702)	66.6	Indole-3-carbinol
Battelle Columbus Laboratory	052000706	08/23/04	729	50(5)	38(695)	66.2	Kava kava extract
Battelle Columbus Laboratory	052010704	10/25/04	729	50(5)	43(715)	66.6	N,N-Dimethyl-p-toluidine
Battelle Columbus Laboratory	052032004	08/06/07	729	50(5)	40(711)	66.5	Tetrabromobisphenol A

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 5

			Male				Female	
#All Organs: Benign Tumors								
		38/50 (76%) 36/50 (72%)	33/50 (66%) 38/50 (76%)	34/50 (68%)		25/50 (50%) 24/50 (48%)	17/50 (34%) 22/50 (44%)	26/50 (52%)
Overall Incidence	Total	179/250 (71.6%)	Mean 71.6%	SD 4.56%	Total	114/250 (45.6%)	Mean 45.6%	SD 7.13%
#All Organs: Malignant Tumors								
		35/50 (70%) 29/50 (58%)	27/50 (54%) 21/50 (42%)	32/50 (64%)		28/50 (56%) 21/50 (42%)	19/50 (38%) 18/50 (36%)	19/50 (38%)
Overall Incidence	Total	144/250 (57.6%)	Mean 57.6%	SD 10.62%	Total	105/250 (42%)	Mean 42%	SD 8.12%
#All Organs: Malignant and Benign To		44/50 (88%)	48/50 (96%)	47/50 (94%)		35/50 (70%)	30/50 (60%)	39/50 (78%)
Overall Incidence	Total	45/50 (90%) 231/250 (92.4%)	47/50 (94%) Mean 92.4%	SD 3.29%	Total	35/50 (70%) 171/250 (68.4%)	32/50 (64%) Mean 68.4%	SD 6.84%
#All Organs: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 2/50 (4%)	2/50 (4%)		0/50 (0%) 1/50 (2%)	1/50 (2%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	4/250 (1.6%)	Mean 1.6%	SD 2.19%	Total	3/250 (1.2%)	Mean 1.2%	SD 1.1%
#All Organs: Hemangiosarcoma								
		9/50 (18%) 8/50 (16%)	4/50 (8%) 1/50 (2%)	6/50 (12%)		2/50 (4%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	1/50 (2%)
Overall Incidence	Total	28/250 (11.2%)	Mean 11.2%	SD 6.42%	Total	4/250 (1.6%)	Mean 1.6%	SD 1.67%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 6

			Male				Female			
#All Organs: Hemangiosarcoma or Hemangioma  9/50 (18%) 4/50 (8%) 8/50 (16%) 2/50 (4%) 1/50 (2%) 1/50 (2%)										
		9/50 (18%) 8/50 (16%)	4/50 (8%) 3/50 (6%)	8/50 (16%)		2/50 (4%) 1/50 (2%)	1/50 (2%) 2/50 (4%)	1/50 (2%)		
Overall Incidence	Total	32/250 (12.8%)	Mean 12.8%	SD 5.4%	Total	7/250 (2.8%)	Mean 2.8%	SD 1.1%		
#All Organs: Histiocytic Sarcoma										
		0/50 (0%) 0/50 (0%)	2/50 (4%) 0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	1/50 (2%) 1/50 (2%)	3/50 (6%)		
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	6/250 (2.4%)	Mean 2.4%	SD 2.19%		
#All Organs: Malignant Lymphoma: His	stiocytic, Lym	1/50 (2%)	3/50 (6%)	2/50 (4%)		11/50 (22%)	6/50 (12%)	6/50 (12%)		
	stiocytic, Lym	-		= =		11/50 (22%)	6/50 (12%)	6/50 (12%)		
Malignant Lymphoma: His	stiocytic, Lym Total	-		= =	Total	11/50 (22%) 15/50 (30%) 47/250 (18.8%)	6/50 (12%) 9/50 (18%) Mean 18.8%	6/50 (12%) SD 7.56%		
Malignant Lymphoma: His		1/50 (2%) 4/50 (8%) 13/250 (5.2%)	3/50 (6%) 3/50 (6%) Mean 5.2%	2/50 (4%) SD 2.28%	Total	15/50 (30%) 47/250 (18.8%)	9/50 (18%) Mean 18.8%	SD 7.56%		
Malignant Lymphoma: His  Overall Incidence  #All Organs:		1/50 (2%) 4/50 (8%)	3/50 (6%) 3/50 (6%)	2/50 (4%)	Total	15/50 (30%)	9/50 (18%)	,		
Malignant Lymphoma: His Overall Incidence #All Organs: Mesothelioma: Benign		1/50 (2%) 4/50 (8%) 13/250 (5.2%) 0/50 (0%)	3/50 (6%) 3/50 (6%) Mean 5.2% 0/50 (0%)	2/50 (4%) SD 2.28%	Total Total	15/50 (30%) 47/250 (18.8%) 0/50 (0%)	9/50 (18%) Mean 18.8% 	SD 7.56%		
Malignant Lymphoma: His  Overall Incidence  #All Organs:  Mesothelioma: Benign  Overall Incidence	Total Total	1/50 (2%) 4/50 (8%) 13/250 (5.2%) 0/50 (0%) 0/50 (0%) 0/250 (0%)	3/50 (6%) 3/50 (6%) Mean 5.2% 0/50 (0%) 0/50 (0%)	2/50 (4%) SD 2.28%  0/50 (0%)		15/50 (30%) 47/250 (18.8%) 0/50 (0%) 0/50 (0%)	9/50 (18%) Mean 18.8% 0/50 (0%) 0/50 (0%)	SD 7.56% 0/50 (0%)		
Malignant Lymphoma: His Overall Incidence  #All Organs:     Mesothelioma: Benign  Overall Incidence  #All Organs:	Total Total	1/50 (2%) 4/50 (8%) 13/250 (5.2%) 0/50 (0%) 0/50 (0%) 0/250 (0%)	3/50 (6%) 3/50 (6%) Mean 5.2% 0/50 (0%) 0/50 (0%)	2/50 (4%) SD 2.28%  0/50 (0%)		15/50 (30%) 47/250 (18.8%) 0/50 (0%) 0/50 (0%)	9/50 (18%) Mean 18.8% 0/50 (0%) 0/50 (0%)	SD 7.56% 0/50 (0%)		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 7

			Male				Female	
#All Organs: Mesothelioma: Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#All Organs: Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/250 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma or Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/250 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Adenoma								
		1/50 (2%) 3/50 (6%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	2/49 (4%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	5/250 (2%)	Mean 2%	SD 2.45%	Total	2/249 (0.8%)	Mean 0.82%	SD 1.83%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1 Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 8

			Male				Female					
*Adrenal Cortex: Plasma Cell Tumor Malignant												
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0%	SD 0%				
*Adrenal Medulla: Pheochromocytoma Bo	enign											
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 2/50 (4%)	0/49 (0%) 1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	3/249 (1.2%)	Mean 1.2%	SD 1.79%				
*Adrenal Medulla: Pheochromocytoma M	alignant											
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0%	SD 0%				
*Adrenal Medulla: Pheochromocytoma: B	Benign, Complex,	, Malignant, NOS										
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 2/50 (4%)	0/49 (0%) 1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	3/249 (1.2%)	Mean 1.2%	SD 1.79%				
#Blood Vessel: Hemangioma												
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 9

			Male				Female	
Bone Marrow: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/250 (0%)	Mean 0%	SD 0%
*Bone Marrow: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	2/50 (4%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%	Total	0/250 (0%)	Mean 0%	SD 0%
*Bone Marrow: Mast Cell Tumor Maligna								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Bone Marrow: Plasma Cell Tumor Malig	nant							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Bone Marrow: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

**Page:** 10

Report Date: 06/05/2013

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male					Female	
Bone: Fibroma									
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50	(0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%		Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Bone: Hemangiosarcoma									
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50	(0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%		Total	0/250 (0%)	Mean 0%	SD 0%
Bone: Osteoma									
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50	(0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%		Total	0/250 (0%)	Mean 0%	SD 0%
Bone: Osteosarcoma									•••••
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50	(0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%		Total	0/250 (0%)	Mean 0%	SD 0%
Bone: Osteosarcoma or Osteoma									
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50	(0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%		Total	0/250 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 11

			Male				Female	
#Bone: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Brain: Granular Cell Tumor Ben	ign							
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/250 (0%)	Mean 0%	SD 0%
Brain: Meningioma Benign								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Brain: Meningioma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Brain: Meningioma: Benign, Mal	lignant, NOS							
-		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

**Page:** 12

Report Date: 06/05/2013

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Species: MICE Strain: B6C3F1

Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
*Brain: Oligodendroglioma Ma	lignant							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma, Gli	ioma, or Astrocy	rtoma						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
*Brain: Schwannoma Malignan	nt							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

#### **Toxicology Data Management System**

**Page:** 13

Mean 6.4%

SD 3.58%

Report Date: 06/05/2013

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Male **Female #Coagulating Gland: Granular Cell Tumor** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/250 (0.4%) Mean 0.4% SD 0.89% Total 0/250 (0%) Mean 0% SD 0% #Coagulating Gland: Sarcoma (0%) (0%) 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 0/250 (0%) Mean 0% SD 0% Total 0/250 (0%) Mean 0% SD 0% #Esophagus: **Squamous Cell Carcinoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total 0/250 (0%) Mean 0% SD 0% #Eve: **Melanoma Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total 0/250 (0%) Mean 0% SD 0% #Harderian Gland: Adenoma 4/50 (8%)6/50 (12%)5/50 (10%)5/50 (10%)3/50 (6%)(10%) 11/50 (22%)7/50 (14%)1/50 (2%)2/50 (4%)

SD 5.4%

Total

16/250 (6.4%)

Total

33/250 (13.2%)

Mean 13.2%

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 14

			Male				Female	
#Harderian Gland: Carcinoma								
		3/50 (6%) 0/50 (0%)	1/50 (2%) 1/50 (2%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	5/250 (2%)	Mean 2%	SD 2.45%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%
#Harderian Gland: Carcinoma or Adenoma								
		7/50 (14%) 11/50 (22%)	7/50 (14%) 8/50 (16%)	5/50 (10%)		6/50 (12%) 1/50 (2%)	3/50 (6%) 3/50 (6%)	5/50 (10%)
Overall Incidence	Total	38/250 (15.2%)	Mean 15.2%	SD 4.38%	Total	18/250 (7.2%)	Mean 7.2%	SD 3.9%
*Heart: Hemangiosarcoma				•••••				
•		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Intestine Large: Cecum: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 15

			Male				Female	
#Intestine Large: Cecum: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Leiomyoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Leiomyosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Intestine Large: Colon/Rectu Leiomyosarcoma	ım:							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Adenoma								
		0/50 (0%) 0/50 (0%)	2/50 (4%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	1/50 (2%)
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 16

			Male				Female	
#Intestine Small: Duodenum: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Leiomyosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Polyp Adenomatous								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Page: 17

Mean 0.4%

SD 0.89%

Report Date: 06/05/2013

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC Male **Female** #Intestine Small: Ileum: **Polyp Adenomatous** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total 0/250 (0%) Mean 0% SD 0% #Intestine Small: Jejunum: Adenoma (2%) 0/50 (0%) 0/50 (0%)1/50 1/50 (2%)0/50 (0%)1/50 (2%)(2%) 0/50 (0%)1/50 0/50 (0%)0/50 (0%)SD 1.1% **Overall Incidence** Total 3/250 (1.2%) Mean 1.2% Total 1/250 (0.4%) Mean 0.4% SD 0.89% #Intestine Small: Jejunum: Carcinoma 1/50 (2%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)(2%)0/50 (0%)1/50 0/50 (0%)0/50 (0%)**Overall Incidence** Total 3/250 (1.2%) Mean 1.2% SD 1.1% Total 0/250 (0%) Mean 0% SD 0% #Intestine Small: Jejunum: Hemangiosarcoma 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total 0/250 (0%) Mean 0% SD 0% #Intestine Small: Jejunum: Leiomyosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 0%

Total

1/250 (0.4%)

Total

......

0/250 (0%)

Mean 0%

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

### **Toxicology Data Management System**

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 18

			Male				Female	
#Intestine Small: Site Uns Adenoma	pecified:							
		0/50 (0%) 0/50 (0%)	3/50 (6%) 1/50 (2%)	2/50 (4%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	2/50 (4%)
Overall Incidence	Total	6/250 (2.4%)	Mean 2.4%	SD 2.61%	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%
#Intestine Small: Site Uns Carcinoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.1%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Uns Carcinoma or Adenoma	•	1/50 (2%)	3/50 (6%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	0/50 (0%) 9/250 (3.6%)	2/50 (4%) Mean 3.6%	SD 2.61%	Total	0/50 (0%) 3/250 (1.2%)	1/50 (2%) Mean 1.2%	SD 1.79%
#Intestine Small: Site Uns Hemangiosarcoma	pecified:							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Uns Leiomyosarcoma	pecified:							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

**Page:** 19

Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Intestine Small: Site Unspec	cified:							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma								
		1/50 (2%) 1/50 (2%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.1%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
*Islets, Pancreatic: Carcinoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/250 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma								
		1/50 (2%) 2/50 (4%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	4/250 (1.6%)	Mean 1.6%	SD 1.67%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
*Kidney: Pelvis and Transitio Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE Strain: B6C3F1

#### **Toxicology Data Management System**

Route: GAVAGE

Vehicle: CORN OIL

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

rumor incidend

Length of Study: CHRONIC

**Page:** 20

			Male				Female	
*Kidney: Pelvis and Transition Carcinoma or Adenoma	onal Epitheli	um:						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Adenoma								•••••
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	0/250 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma						•••••		•••••
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	0/250 (0%)	Mean 0%	SD 0%
'Kidney: Renal Tubule: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/250 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 21

			Male				Female	
Kidney: Renal Tubule: Hemangiosarcoma								,
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Plasma Cell Tumor Malign								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
'Kidney: Renal Tubule: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Liver: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 2/50 (4%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Liver: Hemangiosarcoma								
		9/50 (18%) 6/50 (12%)	4/50 (8%) 0/50 (0%)	5/50 (10%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	24/250 (9.6%)	Mean 9.6%	SD 6.54%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 22 Report Date: 06/05/2013

			Male				Female	
Liver: Hepatoblastoma								
		3/50 (6%)	3/50 (6%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/50 (2%) 9/250 (3.6%)	2/50 (4%) Mean 3.6%	SD 2.61%	Total	0/50 (0%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%
		9/230 (3.076)				1/230 (0.476)		
Liver: Hepatocellular Adenom	na							
		31/50 (62%)	26/50 (52%)	27/50 (54%)		17/50 (34%)	7/50 (14%)	8/50 (16%)
		29/50 (58%)	32/50 (64%)	05 - 101		17/50 (34%)	13/50 (26%)	05
Overall Incidence	Total	145/250 (58%)	Mean 58%	SD 5.1%	Total	62/250 (24.8%)	Mean 24.8%	SD 9.55%
Liver: Hepatocellular Carcino	ma							
		22/50 (44%)	12/50 (24%)	20/50 (40%)		9/50 (18%)	6/50 (12%)	3/50 (6%)
		22/50 (44%)	11/50 (22%)			6/50 (12%)	2/50 (4%)	
Overall Incidence	Total	87/250 (34.8%)	Mean 34.8%	SD 10.92%	Total	26/250 (10.4%)	Mean 10.4%	SD 5.55%
Liver: Hepatocellular Carcino	ma or Hepatobl	astoma						
		24/50 (48%) 22/50 (44%)	15/50 (30%) 12/50 (24%)	20/50 (40%)		10/50 (20%) 6/50 (12%)	6/50 (12%) 2/50 (4%)	3/50 (6%)
Overall Incidence	Total	93/250 (37.2%)	Mean 37.2%	SD 9.96%	Total	27/250 (10.8%)	Mean 10.8%	SD 6.26%
*Liver: Hepatocellular Carcino		ellular Adenoma						
-	•	39/50 (78%) 38/50 (76%)	35/50 (70%) 39/50 (78%)	38/50 (76%)		20/50 (40%) 20/50 (40%)	12/50 (24%) 15/50 (30%)	10/50 (20%)
Overall Incidence	Total	189/250 (75.6%)	Mean 75.6%	SD 3.29%	Total	77/250 (30.8%)	Mean 30.8%	SD 9.12%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date: 06/05/2013

**Page:** 23

			Male				Female	
*Liver:						,		
Hepatocellular Carcinoma	a, Hepatocellu	•						
		39/50 (78%) 38/50 (76%)	36/50 (72%) 39/50 (78%)	38/50 (76%)		20/50 (40%) 20/50 (40%)	12/50 (24%) 15/50 (30%)	10/50 (20%)
Overall Incidence	Total	190/250 (76%)	Mean 76%	SD 2.45%	Total	77/250 (30.8%)	Mean 30.8%	SD 9.12%
Liver: Hepatocholangiocarcinon								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	4/50 (8%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/250 (1.6%)	Mean 1.6%	SD 3.58%	Total	0/250 (0%)	Mean 0%	SD 0%
*Liver: Hepatocholangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Liver: Ito Cell Tumor Benign		•••••	•••••			•••••		
- -		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/250 (0%)	Mean 0%	SD 0%
Liver: Mast Cell Tumor Malignar	nt							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

# **Toxicology Data Management System**

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 24

			Male				Female	
Liver:								
Plasma Cell Tumor Ma	alignant							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Liver: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Lung: Alveolar/Bronchiolar <i>A</i>	Adenoma							
		8/50 (16%)	4/50 (8%)	9/50 (18%)		0/50 (0%)	1/50 (2%)	2/50 (4%)
		11/50 (22%)	6/50 (12%)			2/50 (4%)	5/50 (10%)	
Overall Incidence	Total	38/250 (15.2%)	Mean 15.2%	SD 5.4%	Total	10/250 (4%)	Mean 4%	SD 3.74%
Lung: Alveolar/Bronchiolar (	Carcinoma							
		11/50 (22%)	4/50 (8%)	2/50 (4%)		1/50 (2%)	2/50 (4%)	2/50 (4%)
		2/50 (4%)	4/50 (8%)			0/50 (0%)	1/50 (2%)	
verall Incidence	Total	23/250 (9.2%)	Mean 9.2%	SD 7.43%	Total	6/250 (2.4%)	Mean 2.4%	SD 1.67%
Lung: Alveolar/Bronchiolar (	Carcinoma or Alv	veolar/Bronchiolar Adeno	ma					
		17/50 (34%)	8/50 (16%)	11/50 (22%)		1/50 (2%)	3/50 (6%)	4/50 (8%)
		13/50 (26%)	10/50 (20%)			2/50 (4%)	6/50 (12%)	
Overall Incidence	Total	59/250 (23.6%)	Mean 23.6%	SD 6.84%	Total	16/250 (6.4%)	Mean 6.4%	SD 3.85%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

\*Lung:

\*Lung:

#### **Toxicology Data Management System**

**Page: 25** 

Report Date: 06/05/2013

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Male **Female** Hemangiosarcoma 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 2/250 (0.8%) Mean 0.8% SD 1.1% Total 0/250 (0%) Mean 0% SD 0% **Plasma Cell Tumor Malignant** (0%) 0/50 (0%) 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total 0/250 (0%) Mean 0% SD 0% ...... **#Lymph Node: Plasma Cell Tumor Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total 0/250 (0%) Mean 0% SD 0% #Lymph Node, Bronchial: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total 0/250 (0%) Mean 0% SD 0% #Lymph Node, Mandibular:

Total

......

0/50

0/50

0/250 (0%)

(0%)

(0%)

0/50

0/50

Mean 0%

(0%)

(0%)

0/50

SD 0%

(0%)

0/50

0/50

0/250 (0%)

Total

(0%)

(0%)

0/50

0/50

(0%)

(0%)

Mean 0%

0/50

SD 0%

(0%)

Hemangiosarcoma

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 26

			Male				Female	
#Lymph Node, Mandibular: Mast Cell Tumor Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Lymph Node, Mandibular: Plasma Cell Tumor Maligna	nt							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Lymph Node, Mediastinal: Mast Cell Tumor Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangiosarcoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/250 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Plasma Cell Tumor Maligna	nt							
•		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Page: 27

Report Date: 06/05/2013

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Mammary Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Mammary Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%
Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%
Mammary Gland: Fibroadenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Mammary Gland: Fibroma, Fibroadenoma	or Adenoma							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	0/30 (0%) Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

Page: 28

			Male				Female			
#Mammary Gland: Fibroma, Fibroadenoma, Carcinoma, or Adenoma										
r ibroma, r ibroductionic	i, caromoma, or	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%		
Mesentery: Hemangioma										
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%		
Mesentery: Hemangiosarcoma										
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	0/50 (0%) Mean 0%	SD 0%		
Mesentery: Lipoma										
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%		
Mesentery: Sarcoma										
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 29 Report Date: 06/05/2013

Species: MICE Strain: B6C3F1 Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
*Nose: Adenoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
*Nose: Hemangiosarcoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Papilloma Squamous	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 1/250 (0.4%)	0/50 (0%) 1/50 (2%) Mean 0.4%	0/50 (0%) SD 0.89%
Oral Cavity (Oral Mucos Squamous Cell Carcin		ynx, Tooth, Gingiva):						
,		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%
#Oral Cavity (Oral Mucos	sa, Tongue, Phar	ynx, Tooth, Gingiva): Squamous, or Papilloma						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%) 2/50 (4%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%		3/250 (1.2%)	Mean 1.2%	SD 1.79%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 30 Report Date: 06/05/2013

			Male					Female	
Oral Mucosa: Squamous Cell Carcino	ma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0	%)		1/50 (2%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%		Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%
Ovary: Choriocarcinoma									
							1/50 (2%)	0/50 (0%)	0/49 (0%)
Overall Incidence						Total	0/50 (0%) 1/249 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%
Ovary: Cystadenocarcinoma									
•							0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence						Total	0/50 (0%) 0/249 (0%)	0/50 (0%) Mean 0%	SD 0%
Ovary: Cystadenoma									
·							2/50 (4%) 1/50 (2%)	1/50 (2%) 2/50 (4%)	5/49 (10%)
Overall Incidence						Total	11/249 (4.42%)	Mean 4.44%	SD 3.37%
Ovary: Granulosa Cell Tumor B	enign								
							0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence						Total	0/50 (0%) 0/249 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 31

	Male		Female	
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)
Overall Incidence	Tot		Mean 0%	SD 0%
*Ovary:				
Hemangioma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)
Overall Incidence	Tot	al 0/249 (0%)	Mean 0%	SD 0%
*Ovary: Hemangiosarcoma				
		1/50 (2%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Tot	0/50 (0%) al 1/249 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%
*Ovary: Luteoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/49 (2%)
Overall Incidence	Tot	al 1/249 (0.4%)	Mean 0.41%	SD 0.91%
*Ovary: Plasma Cell Tumor Malignant				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)
Overall Incidence	Tot	, ,	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 32 Report Date: 06/05/2013

	Male			Female	
Ovary:					
Sarcoma			0/50 (00/)	0/50 (00/)	0/40 (00/)
			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)
Overall Incidence		Total	0/249 (0%)	Mean 0%	SD 0%
				·····	
Ovary: Teratoma Benign					
•			0/50 (0%)	0/50 (0%)	0/49 (0%)
			0/50 (0%)	0/50 (0%)	
Overall Incidence		Total	0/249 (0%)	Mean 0%	SD 0%
Ovary: Teratoma Malignant			•••••		•••••
-			0/50 (0%)	0/50 (0%)	0/49 (0%)
			0/50 (0%)	0/50 (0%)	
Overall Incidence		Total	0/249 (0%)	Mean 0%	SD 0%
Ovary: Tubulostromal Adenoma			•••••		
			0/50 (0%)	1/50 (2%)	0/49 (0%)
			1/50 (2%)	0/50 (0%)	
Overall Incidence		Total	2/249 (0.8%)	Mean 0.8%	SD 1.1%
Ovary: Yolk Sac Carcinoma			•••••		•••••
			0/50 (0%)	0/50 (0%)	0/49 (0%)
			0/50 (0%)	0/50 (0%)	,
Overall Incidence		Total	0/249 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

**Page:** 33

Report Date: 06/05/2013

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Pancreas: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/249 (0%) **Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total Mean 0% SD 0% \*Pancreas: Carcinoma or Adenoma (0%)(0%) (0%) 0/50 0/50 0/50 (0%)0/50 (0%)0/50 0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total 0/249 (0%) Mean 0% SD 0% ...... \*Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma 0/49 (0%)0/50 (0%)0/49 (0%)4/50 (8%)3/49 (6%)2/50 (4%)0/50 (0%)0/50 (0%)0/48 (0%)1/50 (2%)**Overall Incidence** Total 0/248 (0%) Mean 0% SD 0% Total 10/247 (4.05%) Mean 4.02% SD 3.18% \*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma 0/49 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/48 (0%)0/50 (0%)Overall Incidence Total 0/248 (0%) Mean 0% SD 0% Total 0/247 (0%) Mean 0% SD 0% \*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma

0/49

SD 0%

(0%)

4/50

0/48

10/247 (4.05%)

Total

(8%)

(0%)

3/49

1/50

(6%)

(2%)

Mean 4.02%

2/50

SD 3.18%

(4%)

Total

0/49

0/50

0/248 (0%)

(0%)

(0%)

0/50

0/50

Mean 0%

(0%)

(0%)

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

**Page:** 34

			Male				Female	
*Pituitary Gland: Pars Intern Adenoma	nedia:							
		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/49 (2%)		1/50 (2%) 0/48 (0%)	1/49 (2%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%	Total	3/247 (1.21%)	Mean 1.21%	SD 1.1%
*Pituitary Gland: Pars Intern Carcinoma or Adenoma	nedia:							
		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/49 (2%)		1/50 (2%) 0/48 (0%)	1/49 (2%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%	Total	3/247 (1.21%)	Mean 1.21%	SD 1.1%
*Salivary Glands: Adenoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%
*Salivary Glands: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%
*Salivary Glands: Hemangiosarcoma								
-		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/249 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 35 Report Date: 06/05/2013

			Male				Female	
Salivary Glands: Mast Cell Tumor Malignant	i							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0%	SD 0%
Salivary Glands: Myxoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma			•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Hemangiosarcoma			•••••				•••••	•••••
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Skeletal Muscle: Rhabdomyosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	3/50 (6%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	3/250 (1.2%)	Mean 1.2%	SD 2.68%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 36

			Male		Female	
#Skeletal Muscle: Rhabdomyosarcoma or	Rhabdomyoma					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0 0/50 (0%)	,	(0%) 0/50 (0%) 3/50 (0%) 0/50 (0%)	(6%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 3/250 (1.2%	•	2.68%
#Skeletal Muscle: Sarcoma						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0 0/50 (0%)	,	(0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	(0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 0/250 (0%	Mean 0% SD	0%
#Skin: Basal Cell Carcinoma		•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0 0/50 (0%)	,	(2%) 0/50 (0%) 0/50 (0%) 1/50 (2%)	(0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 2/250 (0.89	%) Mean 0.8% SD	1.1%
#Skin:		s Tumor (malignant or N	os)			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0 0/50 (0%)	,	(2%) 0/50 (0%) 0/50 (0%) 1/50 (2%)	(0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 2/250 (0.89	,	1.1%
#Skin:	asal Cell Adend	oma, Basosquamous Tur	or (benign, malignant or			
•		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0 0/50 (0%)	,	(2%) 0/50 (0%) 0/50 (0%) 1/50 (2%)	(0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 2/250 (0.89	` ,	1.1%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 37

			Male				Female	
#Skin: Basal or Sq. Cell Carcino Adenoma, Papilloma, Sq	oma, Carcinom Papilloma, Ke	na, Basosq. Tumor (M or I eratoacanthoma, Trichoep	3), Basal Cell Adenoma, ithelioma					
	•	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		1/50 (2%) 1/50 (2%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)		SD 0.89%	Total	3/250 (1.2%)	Mean 1.2%	SD 1.1%
#Skin: Fibroma, Fibrosarcoma,	Sarcoma, Myx		ibrous Histiocytoma	0/50 (0%)		3/50 (6%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0,00 (0,0)		2/50 (4%)	1/50 (2%)	(0,0)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	7/250 (2.8%)	Mean 2.8%	SD 2.28%
#Skin: Fibrosarcoma		0/50 (00)	4/50 (00()	0/50 (00)		0/50 (004)	0/50 (00/)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 2/50 (4%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	` ,	SD 0.89%	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%
≇Skin: Fibrosarcoma, Sarcoma,	Myxosarcoma	a, or Fibrous Histiocytom 0/50 (0%) 0/50 (0%)	a 1/50 (2%) 1/50 (2%)	0/50 (0%)		3/50 (6%) 2/50 (4%)	1/50 (2%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	7/250 (2.8%)	Mean 2.8%	SD 2.28%
#Skin: Fibrous Histiocytoma	••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 38

			Male				Female	
#Skin: Granular Cell Tumor Be	nign							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Skin: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Skin: Keratoacanthoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Skin: Lipoma								
•		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/250 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

**Page:** 39

Report Date: 06/05/2013

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups
Route: GAVAGE
Vehicle: CORN OIL

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

			Male				Female	
≮Skin: Liposarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Skin: Mast Cell Tumor Benign								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
≴Skin: Mast Cell Tumor Malignant	•••••							0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Skin: Melanoma Benign			•••••					•••••
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Skin: Melanoma Malignant								
-		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 40

Report Date: 06/05/2013

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC Male **Female** #Skin: **Neural Crest Tumor** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/250 (0%) **Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total Mean 0% SD 0% #Skin: Neurofibroma or Schwannoma benign 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total 0/250 (0%) Mean 0% SD 0% ..... #Skin: Neurofibrosarcoma or Schwannoma (malignant or NOS) (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total 1/250 (0.4%) Mean 0.4% SD 0.89% #Skin: Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) (0%) 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total 1/250 (0.4%) Mean 0.4% SD 0.89% #Skin: Osteosarcoma 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 0.89%

0/50

0/250 (0%)

Total

(0%)

0/50

(0%)

SD 0%

Mean 0%

Total

0/50

1/250 (0.4%)

(0%)

.....

0/50

Mean 0.4%

(0%)

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

### **Toxicology Data Management System**

Page: 41

Report Date: 06/05/2013

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Male **Female** #Skin: Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)3/50 (6%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/250 (0.4%) Mean 0.4% SD 0.89% Total 4/250 (1.6%) Mean 1.6% SD 2.61% #Skin: Schwannoma Benign (0%)(0%)0/50 0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total 0/250 (0%) SD 0% #Skin: Schwannoma Malignant 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total 1/250 (0.4%) Mean 0.4% SD 0.89% #Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 0/50 0/50 1/50 (2%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total 2/250 (0.8%) Mean 0.8% SD 1.1% #Skin: **Squamous Cell Papilloma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 0%

0/50

0/250 (0%)

Total

(0%)

0/50

(0%)

SD 0%

Mean 0%

Total

0/50

0/250 (0%)

(0%)

0/50

Mean 0%

(0%)

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Control Animal Groups Report Date: 06/05/2013
AGE

Page: 42

			Male				Female	
#Skin: Squamous Cell Papillor	na or Papilloma							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	0 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0	0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin:	ma Danilloma S	Squamous Cell Carcinom	a or Koratoacanthoma					
Squamous Cen Fapinor	na, Fapinoma, S	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 1/50 (2%)	0 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4% SD 0.	.89%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Skin: Squamous Cell Papillor  Overall Incidence	na, Papilloma, o Total	or Keratoacanthoma 0/50 (0%) 0/50 (0%) 1/250 (0.4%)	0/50 (0%) 0/50 1/50 (2%) Mean 0.4% SD 0.	,	Total	0/50 (0%) 1/50 (2%) 1/250 (0.4%)	0/50 (0%) 0/50 (0%) Mean 0.4%	0/50 (0%) SD 0.89%
Skin: Sebaceous Gland: Adenoma		0/50 (0%)	0/50 (0%) 0/50	0 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0% SD (	0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	0 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0	0%	Total	0/250 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 43

			Male				Female	
#Spinal Cord: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
*Spleen: Hemangioma								
		0/50 (0%) 0/48 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma								
		0/50 (0%) 3/48 (6%)	1/50 (2%) 1/50 (2%)	2/50 (4%)		1/50 (2%) 0/49 (0%)	0/50 (0%) 1/50 (2%)	0/49 (0%)
Overall Incidence	Total	7/248 (2.82%)	Mean 2.85%	SD 2.37%	Total	2/248 (0.81%)	Mean 0.8%	SD 1.1%
'Spleen: Mast Cell Tumor Malignant					•••••			
		0/50 (0%) 0/48 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	1/49 (2%)
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%
*Spleen: Plasma Cell Tumor Malignar	nt							
Š		0/50 (0%) 0/48 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 44

			Male				Female	
#Stomach, Forestomach: Squamous Cell Carcinoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	0/250 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach:								
Squamous Cell Carcinoma	or Papillom	0/50 (0%) 1/50 (2%)	2/50 (4%) 5/50 (10%)	9/50 (18%)		2/50 (4%) 1/50 (2%)	1/50 (2%) 0/50 (0%)	3/50 (6%)
Overall Incidence	Total	17/250 (6.8%)	Mean 6.8%	SD 7.29%	Total	7/250 (2.8%)	Mean 2.8%	SD 2.28%
Stomach, Forestomach: Squamous Cell Papilloma								
		0/50 (0%) 1/50 (2%)	1/50 (2%) 5/50 (10%)	8/50 (16%)		2/50 (4%) 1/50 (2%)	1/50 (2%) 0/50 (0%)	3/50 (6%)
Overall Incidence	Total	15/250 (6%)	Mean 6%	SD 6.78%	Total	7/250 (2.8%)	Mean 2.8%	SD 2.28%
Stomach, Glandular: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Stomach, Glandular: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

> Route: GAVAGE Vehicle: CORN OIL

**Page:** 45

Report Date: 06/05/2013

Strain: B6C3F1 Length of Study: CHRONIC Male Female

			Male				Female	
#Stomach, Glandular: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Testes: Adenoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%				
Testes: Hemangioma								•••••
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%				
Thymus: Neoplasm NOS	•••••				••••			
		0/50 (0%) 0/48 (0%)	0/49 (0%) 0/47 (0%)	0/48 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/242 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0%	SD 0%
Thymus: Thymoma Benign								
		0/50 (0%) 0/48 (0%)	1/49 (2%) 0/47 (0%)	0/48 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/242 (0.41%)	Mean 0.41%	SD 0.91%	Total	0/249 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page**: 46

			Male				Female	
Thymus: Thymoma Malignant								
		0/50 (0%) 0/48 (0%)	0/49 (0%) 0/47 (0%)	0/48 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/242 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Malig								
		0/50 (0%) 0/48 (0%)	1/49 (2%) 0/47 (0%)	0/48 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/242 (0.41%)	Mean 0.41%	SD 0.91%	Total	0/249 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma				•••••				
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/249 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/249 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/249 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/249 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%
*Thyroid Gland: Follicular ( Adenoma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/50 (2%) 1/249 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%	Total	0/50 (0%) 1/249 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

# **Toxicology Data Management System**

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 47

			Male				Female	
*Thyroid Gland: Follicular Cel Carcinoma	l:							
		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cel Carcinoma or Adenoma								
		0/49 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%
#Tissue NOS: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Tissue NOS: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Tissue NOS: Plasma Cell Tumor Maligna	nt							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 48

			Male				Female	
#Tissue NOS: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Tongue: Fibroma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinom	a or Papillom	-	0/50 (00/)	0/50 (00/)		0/50 (00/)	0(50 (00))	0(50 (00))
_	a or Papillom	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Squamous Cell Carcinom	a or Papilloma	-	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 1/250 (0.4%)	0/50 (0%) 1/50 (2%) Mean 0.4%	0/50 (0%) SD 0.89%
Squamous Cell Carcinom	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/250 (0.4%)	1/50 (2%) Mean 0.4%	SD 0.89%
Squamous Cell Carcinom Overall Incidence #Tongue:	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0% 0/50 (0%)	,	Total	0/50 (0%) 1/250 (0.4%) 0/50 (0%)	1/50 (2%) Mean 0.4% 0/50 (0%)	,
Squamous Cell Carcinom  Overall Incidence  #Tongue: Squamous Cell Papilloma	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total Total	0/50 (0%) 1/250 (0.4%)	1/50 (2%) Mean 0.4%	SD 0.89%
Squamous Cell Carcinom Overall Incidence #Tongue: Squamous Cell Papilloma Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/250 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	SD 0% 0/50 (0%)		0/50 (0%) 1/250 (0.4%) 0/50 (0%) 0/50 (0%)	1/50 (2%) Mean 0.4% 0/50 (0%) 1/50 (2%)	SD 0.89% 0/50 (0%)
Squamous Cell Carcinom Overall Incidence  #Tongue: Squamous Cell Papilloma Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/250 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	SD 0% 0/50 (0%)		0/50 (0%) 1/250 (0.4%) 0/50 (0%) 0/50 (0%)	1/50 (2%) Mean 0.4% 0/50 (0%) 1/50 (2%)	SD 0.89% 0/50 (0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 49

			Male				Female	
#Urethra: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Urinary Bladder: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Urinary Bladder: Plasma Cell Tumor Mali	gnant	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/30 (0/0)		0/50 (0%)	0/50 (0%)	0/30 (0/0)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
tUterus: Adenoma								
						0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/250 (0%)	Mean 0%	SD 0%
Uterus: Carcinoma								
						0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/250 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

**Page:** 50

Report Date: 06/05/2013

Route: GAVAGE
Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Uterus: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% #Uterus: Leiomyoma (0%) 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% #Uterus: Leiomyosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% #Uterus: **Polyp Stromal** 1/50 (2%)0/50 (0%)2/50 (4%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 3/250 (1.2%) Mean 1.2% SD 1.79% #Uterus: Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL **Page:** 51

			Male				Female	
#Uterus: Sarcoma Stromal								
						1/50 (2%) 0/50 (0%)	0/50 (0%) 2/50 (4%)	0/50 (0%)
Overall Incidence					Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%
#Uterus: Sarcoma Stromal or Polyp	Stromal							
						2/50 (4%) 0/50 (0%)	0/50 (0%) 2/50 (4%)	2/50 (4%)
Overall Incidence					Total	6/250 (2.4%)	Mean 2.4%	SD 2.19%
#Vagina: Liposarcoma								
						0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/30 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/250 (0%)	Mean 0%	SD 0%
≇Zymbal's Gland: Carcinoma or Adenoma						•••••		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/50 (2%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

**Page:** 52

Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

# **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Southern Research Institute	059903706	06/30/03	729	50(1)	40(701)	53.9	alpha/beta Thujone mixture
					Female		
Southern Research Institute	059903706	06/30/03	731	50(5)	37(668)	64.7	alpha/beta Thujone mixture

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

**Page:** 53

Report Date: 06/05/2013

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male			Female			
#All Organs: Benign Tumors									
-		32/50 (64%)				22/50 (44%)			
Overall Incidence	Total	32/50 (64%)	Mean 64%	SD 0%	Total	22/50 (44%)	Mean 44%	SD 0%	
#All Organs: Malignant Tumors									
Overall Incidence	Total	30/50 (60%) 30/50 (60%)	Mean 60%	SD 0%	Total	19/50 (38%) 19/50 (38%)	Mean 38%	SD 0%	
#All Organs: Malignant and Benign Tu									
		45/50 (90%)				35/50 (70%)			
Overall Incidence	Total	45/50 (90%)	Mean 90%	SD 0%	Total	35/50 (70%)	Mean 70%	SD 0%	
#All Organs: Hemangioma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
All Organs: Hemangiosarcoma									
		4/50 (8%)				1/50 (2%)			
Overall Incidence	Total	4/50 (8%)	Mean 8%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#All Organs: Hemangiosarcoma or He		4/50 (8%)				1/50 (2%)			
Overall Incidence	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
		4/30 (0%)				` '			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

**Page:** 54

				Male				Female			
#All Organs: Histiocytic Sarcoma		,									
		1/50	(2%)				2/50 (4%)				
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%		
#All Organs: Malignant Lymphoma: Hist	iocytic. Lymr	ohocytic. Mixed	. NOS. or	Undifferentiated Ce	ell Type						
	, _,,		(8%)		, , , ,		6/50 (12%)				
Overall Incidence	Total	4/50 (8%)	, ,	Mean 8%	SD 0%	Total	6/50 (12%)	Mean 12%	SD 0%		
#All Organs: Mesothelioma: Benign	•••••						0/50 (0%)				
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#All Organs: Mesothelioma: Benign, Mal	ignant, NOS	0/50	(00()				0/50 (00/)				
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#All Organs: Mesothelioma: Malignant		0/50	(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
All Organs: Osteoma											
		1/50	(2%)				0/50 (0%)				
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

**Page:** 55

Report Date: 06/05/2013

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male		Female			
#All Organs: Osteosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma or Osteom		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Adenoma		2/50 (4%)				1/50 (2%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Adrenal Cortex: Plasma Cell Tumor Malign		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Adrenal Medulla: Pheochromocytoma Beni	gn	0/49 (0%)				0/50 (0%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Malig	nant	1/49 (2%)				0/50 (0%)		
Overall Incidence	Total	1/49 (2.04%)	Mean 2.04%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

**Page:** 56

Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female						
*Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS												
		1/49 (2%)				0/50 (0%)						
Overall Incidence	Total	1/49 (2.04%)	Mean 2.04%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Blood Vessel: Hemangioma												
		0/50 (0%)		<b>25 20</b> /		0/50 (0%)		00.00				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Bone Marrow: Hemangioma												
		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Bone Marrow: Hemangiosarcoma		0/50 (0%)				1/50 (2%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%				
*Bone Marrow: Mast Cell Tumor Malignant												
		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Bone Marrow: Plasma Cell Tumor Maligna						(00)						
		0/50 (0%)		<b>25 20</b> /		1/50 (2%)		00.00				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

**Page:** 57

			Male		Female			
*Bone Marrow: Sarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Bone: Fibroma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Bone: Hemangiosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Bone: Osteoma Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
		, ,				, ,		
#Bone: Osteosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma or Osteoma		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

# **Toxicology Data Management System**

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: METHYLCELLULOSE **Page:** 58

			Male				Female			
#Bone: Sarcoma										
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
Brain: Granular Cell Tumor Benigr										
_		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
'Brain: Meningioma Benign		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
Brain: Meningioma Malignant		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
Brain: Meningioma: Benign, Malig										
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
Brain: Oligodendroglioma Maligna	nt	0/50 (00%)				0/50 (00/)				
Overall Incidence	Total	0/50 (0%)	Maan 00/	CD 00/	Total	0/50 (0%)	Maan 00/	CD 00/		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

**Page:** 59

			Male			Female			
*Brain: Oligodendroglioma, Gliom	na, or Astrocy	toma 0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Brain: Schwannoma Malignant		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
*Clitoral/Preputial Gland: Hemangioma						(201)			
Overall Incidence	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%	
*Clitoral/Preputial Gland: Hemangiosarcoma		0/49 (0%)				0/48 (0%)			
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%	
#Coagulating Gland: Granular Cell Tumor									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Coagulating Gland: Sarcoma		0/50 /00/				0/50 /00/			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

**Page:** 60

			Male				Female			
#Esophagus: Squamous Cell Carcinoma										
-		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Eye: Melanoma Malignant										
_		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Harderian Gland: Adenoma										
		8/50 (16%)				5/50 (10%)				
Overall Incidence	Total	8/50 (16%)	Mean 16%	SD 0%	Total	5/50 (10%)	Mean 10%	SD 0%		
#Harderian Gland: Carcinoma		2/50 (4%)				1/50 (2%)				
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
#Harderian Gland: Carcinoma or Adenoma										
		10/50 (20%)				6/50 (12%)				
Overall Incidence	Total	10/50 (20%)	Mean 20%	SD 0%	Total	6/50 (12%)	Mean 12%	SD 0%		
*Heart: Hemangiosarcoma		0/50 (00%)				0/50 (00/)				
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: METHYLCELLULOSE

Page: 61

				Male			Female			
#Intestine Large: Cecum: Adenoma										
Overall Incidence	Total	0/50 (0 0/50 (0%)	)%) Mean	0% SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Large: Cecum: Carcinoma										
Overall Incidence	Total	0/50 (0 0/50 (0%)	)%) Mean	0% SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Large: Cecum: Carcinoma or Adenoma		0/50 (0	)%)			0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean	0% SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Intestine Large: Cecum: Leiomyoma		•	)%)			0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean	0% SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Intestine Large: Cecum: Leiomyosarcoma										
Overall Incidence	Total	0/50 (0%)	0%) Mean	0% SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Large: Colon/Rect Leiomyosarcoma			)%)			0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean	0% SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Page: 62

				Male				Female			
#Intestine Small: Duodenum: Adenoma		,									
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Duodenum: Carcinoma											
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Duodenum: Leiomyosarcoma			(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	(076)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Duodenum: Polyp Adenomatous			(0%)	M 00/	OD 004	T-1-1	0/50 (0%)	M 00/	OD 001		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Ileum: Adenoma											
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Ileum: Carcinoma		0/50	(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	(0/0)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

**Page:** 63

Report Date: 06/05/2013

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female			
#Intestine Small: Ileum: Polyp Adenomatous		200				(201)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Jejunum: Adenoma		0/50 (0%)				0/50 (00)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Jejunum: Carcinoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Jejunum: Hemangiosarcoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Jejunum: Leiomyosarcoma										
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
#Intestine Small: Site Unspe Adenoma	cified:									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

**Page:** 64

			Male	Female								
#Intestine Small: Site Unspecified: Carcinoma												
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
#Intestine Small: Site Unspe Carcinoma or Adenoma	cified:											
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
#Intestine Small: Site Unspe Hemangiosarcoma	cified:					0/50 (00/)						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
#Intestine Small: Site Unspe Leiomyosarcoma		1/50 (2%)				0/50 (0%)						
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
#Intestine Small: Site Unspe Polyp Adenomatous				•••••		•••••						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
*Islets, Pancreatic: Adenoma		4/50 (00)				4/40 (000)						
Overall Incidence	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%	Total	1/48 (2%) 1/48 (2.08%)	Mean 2.08%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

**Page:** 65

			Male			Female				
*Islets, Pancreatic: Carcinoma		0/50 (0%)				0/48 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%		
*Islets, Pancreatic: Carcinoma or Adenoma		4/50 /00/				4/40 (/00/)				
Overall Incidence	Total	4/50 (8%) 4/50 (8%)	Mean 8%	SD 0%	Total	1/48 (2%) 1/48 (2.08%)	Mean 2.08%	SD 0%		
*Kidney: Pelvis and Transitio Carcinoma	onal Epitheliu	0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Kidney: Pelvis and Transitio Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Kidney: Renal Tubule: Adenoma										
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		
*Kidney: Renal Tubule: Carcinoma		0/50 /02/				0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

**Page:** 66

Report Date: 06/05/2013

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Kidney: Renal Tubule: Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangioma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangiosarcoma						0/50 /00/		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Plasma Cell Tumor Maligna	nt	0/50 (0%)	Many 00/	SD 00/	Total	1/50 (2%)	Magn 20/	CD 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
*Kidney: Renal Tubule: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Liver: Hemangioma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

**Page:** 67

			Male			Female			
*Liver: Hemangiosarcoma									
		2/50 (4%)				1/50 (2%)			
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
*Liver: Hepatoblastoma									
		3/50 (6%)				0/50 (0%)			
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Liver: Hepatocellular Adenoma		0.4/50 (400()				40/50 (000)			
Occasional descriptions of	Tatal	24/50 (48%)	M 400/	OD 00/	T-1-1	13/50 (26%)	M 000/	OD 00/	
Overall Incidence	Total	24/50 (48%)	Mean 48%	SD 0%	Total	13/50 (26%)	Mean 26%	SD 0%	
*Liver: Hepatocellular Carcinoma		16/50 (32%)				3/50 (6%)			
Overall Incidence	Total	16/50 (32%)	Mean 32%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%	
*Liver: Hepatocellular Carcinoma o									
•	•	18/50 (36%)				3/50 (6%)			
Overall Incidence	Total	18/50 (36%)	Mean 36%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%	
*Liver: Hepatocellular Carcinoma c		Ilular Adenoma 33/50 (66%)				15/50 (30%)			
Overall Incidence	Total	33/50 (66%)	Mean 66%	SD 0%	Total	15/50 (30%)	Mean 30%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Page: 68

Report Date: 06/05/2013

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male			Female						
*Liver: Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma 33/50 (66%) 15/50 (30%)  Overall Incidence Total 23/50 (66%)  Property Incidence Total 23/50 (66%)  SD 0% Total 15/50 (20%) Total 15/50 (20%) Total 15/50 (20%)												
Overall Incidence	Total	33/50 (66%)	Mean 66%	SD 0%	Total	15/50 (30%)	Mean 30%	SD 0%				
*Liver: Hepatocholangiocarcinom	ıa	2/-2 (22)				2/22 (22)						
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
*Liver: Hepatocholangioma		4/50 (00()				0/50 /00/						
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%				
*Liver: Ito Cell Tumor Benign		0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Liver: Mast Cell Tumor Malignan	t	0/50 (0%)				0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%				
*Liver: Plasma Cell Tumor Malign	ant			•••••								
		0/50 (0%)				1/50 (2%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

Hemangiosarcoma

\*Liver: Sarcoma

\*Lung:

\*Lung:

\*Lung:

\*Lung:

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

......

Alveolar/Bronchiolar Adenoma

Alveolar/Bronchiolar Carcinoma

.....

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

SD 0%

SD 0%

Total

Total

Male **Female** 0/50 (0%)Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% 3/50 (6%)Mean 14% SD 0% Total 3/50 (6%) Mean 6% SD 0% 1/50 (2%)Mean 12% SD 0% Total 1/50 (2%) Mean 2% SD 0% Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma 4/50 (8%) Mean 26% SD 0% Total Mean 8% SD 0% 4/50 (8%) 0/50 (0%)

0/50 (0%)

1/50

1/50 (2%)

(2%)

Page: 69

Mean 0%

Mean 2%

SD 0%

SD 0%

Report Date: 06/05/2013

Total

Total

Total

Total

Total

Total

0/50

0/50 (0%)

7/50

7/50 (14%)

6/50 (12%)

13/50 (26%)

0/50

0/50 (0%)

0/50

0/50 (0%)

(0%)

(14%)

6/50 (12%)

13/50 (26%)

(0%)

(0%)

Mean 0%

Mean 0%

**Plasma Cell Tumor Malignant** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

**Page:** 70

			Male			Female			
#Lymph Node: Plasma Cell Tumor Maligna	ınt								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
#Lymph Node, Bronchial: Hemangiosarcoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Lymph Node, Mandibular: Hemangiosarcoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Lymph Node, Mandibular: Mast Cell Tumor Malignant		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Lymph Node, Mandibular: Plasma Cell Tumor Maligna	nt	0/50 (00/)				4/50 (001)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
#Lymph Node, Mediastinal: Mast Cell Tumor Malignant		<b>15-11</b>				0/20 (00)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Page: 71 Report Date: 06/05/2013

			Male	Female				
#Lymph Node, Mesenteric: Hemangiosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Plasma Cell Tumor Maligna	ant	1/50 (2%)				1/50 (2%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Mammary Gland: Adenoma						0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Mammary Gland: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Mammary Gland: Fibroadenoma		0/50 (09/)				0/50 (09/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

**Page:** 72

Report Date: 06/05/2013

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female					
#Mammary Gland: Fibroma, Fibroadenoma or Adenoma											
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Mammary Gland: Fibroma, Fibroadenoma	Carcinoma or	Adonoma	•••••	•••••							
Fibroffia, Fibroauerioffia	, Carcillollia, Or 7	0/50 (0%)				1/50 (2%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%			
#Mesentery: Hemangioma		0/50 (00/)				0/50 (00/)					
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Mesentery: Hemangiosarcoma											
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Mesentery: Lipoma											
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Mesentery: Sarcoma											
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: METHYLCELLULOSE

**Page:** 73

			Male				Female	
*Nose: Adenoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Nose: Hemangiosarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Papilloma Squamous o	a, Tongue, Phary					0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcino	a, Tongue, Phary							
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos	a, Tongue, Phary					0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Oral Mucosa: Squamous Cell Carcino	oma	0/50 (0%)				0/50 (0%)		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

**Toxicology Data Management System** 

Page: 74

Mean 0%

SD 0%

Report Date: 06/05/2013

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: METHYLCELLULOSE

	Male			Female	
*Ovary: Choriocarcinoma					
Overall Incidence		Total	1/48 (2%) 1/48 (2.08%)	Mean 2.08%	SD 0%
*Ovary:					
Cystadenocarcinoma			0/48 (0%)		
Overall Incidence		Total	0/48 (0%)	Mean 0%	SD 0%
*Ovary: Cystadenoma			•••••		
•			2/48 (4%)		
Overall Incidence		Total	2/48 (4.17%)	Mean 4.17%	SD 0%
Ovary: Granulosa Cell Tumor Benign					
			0/48 (0%)		
Overall Incidence		Total	0/48 (0%)	Mean 0%	SD 0%
Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS					
			0/48 (0%)		
Overall Incidence		Total	0/48 (0%)	Mean 0%	SD 0%
*Ovary: Hemangioma					
-			0/48 (0%)		

Total

0/48 (0%)

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: METHYLCELLULOSE

**Page:** 75

Mal	9		Female	
*Ovary: Hemangiosarcoma				
Overall Incidence	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%
*Ovary: Luteoma				
Overall Incidence	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%
*Ovary: Plasma Cell Tumor Malignant				
Overall Incidence	Total	1/48 (2%) 1/48 (2.08%)	Mean 2.08%	SD 0%
*Ovary: Sarcoma				
Overall Incidence	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%
*Ovary: Teratoma Benign			••••••	
Overall Incidence	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%
*Ovary: Teratoma Malignant				
Overall Incidence	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Page: 76

Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Ovary: **Tubulostromal Adenoma** 0/48 (0%)Overall Incidence Total 0/48 (0%) Mean 0% SD 0% \*Ovary: Yolk Sac Carcinoma 0/48 (0%)**Overall Incidence** Total 0/48 (0%) Mean 0% SD 0% \*Pancreas: Carcinoma 0/50 (0%)0/48 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/48 (0%) Mean 0% SD 0% ..... \*Pancreas: Carcinoma or Adenoma 0/50 (0%)0/48 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/48 (0%) Mean 0% SD 0% \*Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma 0/48 (0%)2/49 (4%)**Overall Incidence** Total 0/48 (0%) Mean 0% SD 0% Total 2/49 (4.08%) Mean 4.08% SD 0% \*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma 0/48 (0%)0/49 (0%)**Overall Incidence** Total 0/48 (0%) Mean 0% SD 0% Total Mean 0% SD 0% 0/49 (0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Page: 77

			Male				Female	
*Pituitary Gland: Pars Dist Carcinoma or Adenoma	alis or Unspecif	fied Site:						
Overall Incidence	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%	Total	2/49 (4%) 2/49 (4.08%)	Mean 4.08%	SD 0%
*Pituitary Gland: Pars Intel Adenoma	rmedia:							
Overall Incidence	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Intel Carcinoma or Adenoma	rmedia:	0/48 (0%)				0/49 (0%)		
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Salivary Glands: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
*Salivary Glands: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

**Page:** 78

			Male				Female	
*Salivary Glands: Mast Cell Tumor Malignant								
		0/50 (0%)				0/49 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Salivary Glands: Myxoma								
		0/50 (0%)				0/49 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%				
		` '						
#Skeletal Muscle: Hemangiosarcoma								
		2/50 (4%)				0/50 (0%)		
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma								
•		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma or Rha	abdomyoma		•••••					
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

**Page**: 79

Report Date: 06/05/2013

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Skeletal Muscle: Sarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma								
• " ' '	<b></b>	0/50 (0%)		05.00/	<b>-</b>	0/50 (0%)		00.00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma o	or Basosquamou	s Tumor (malignant or N 0/50 (0%)	os)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
		oma, Basosquamous Tur	nor (benign, maligna	ant or		0/50 (0%)		
		•	nor (benign, maligna Mean 0%	ant or SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
Basal Cell Carcinoma, NOS), or Trichoepitheli Overall Incidence #Skin: Basal or Sq. Cell Carci	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
Basal Cell Carcinoma, NOS), or Trichoepitheli Overall Incidence #Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S	Total Total  noma, Carcinoma Sq Papilloma, Ker	0/50 (0%) 0/50 (0%) a, Basosq. Tumor (M or E ratoacanthoma, Trichoep 0/50 (0%) 0/50 (0%)	Mean 0%  3), Basal Cell Adeno ithelioma  Mean 0%	SD 0% ma, SD 0%	Total Total	0/50 (0%)	Mean 0% Mean 0%	SD 0% SD 0%
Basal Cell Carcinoma, NOS), or Trichoepitheli Overall Incidence #Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S Overall Incidence	Total Total  noma, Carcinoma Sq Papilloma, Ker	0/50 (0%) 0/50 (0%) a, Basosq. Tumor (M or Eratoacanthoma, Trichoep	Mean 0%  B), Basal Cell Adeno ithelioma  Mean 0%	SD 0% ma, SD 0%		0/50 (0%)		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Page: 80

			Male				Female	
#Skin: Fibrosarcoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%
	10tai	0/50 (0%)			ıoıaı	2/50 (4%)	Wean 4%	3D 0%
#Skin: Fibrosarcoma, Sarcoma	, Myxosarcoma	, or Fibrous Histiocyto 0/50 (0%)	ma			3/50 (6%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%
#Skin: Fibrous Histiocytoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Granular Cell Tumor Be		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Hemangiosarcoma		0/50 (201)				4/50 (00%)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Page: 81

			Male				Female	
#Skin: Keratoacanthoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Lipoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Mast Cell Tumor Benign		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Mast Cell Tumor Malignant		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Melanoma Benign								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

#Skin:

#Skin:

#Skin:

#Skin:

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

**Melanoma Malignant** 

**Neural Crest Tumor** 

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

......

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Male **Female** 0/50 (0%)Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% 0/50 (0%)Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% 0/50 (0%)Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% 1/50 (2%)Mean 0% SD 0% Total Mean 2% SD 0% 1/50 (2%)

Page: 82

Mean 0%

SD 0%

Report Date: 06/05/2013

Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)

Total

Total

Total

Total

Neurofibrosarcoma or Schwannoma (malignant or NOS)

0/50

0/50 (0%)

0/50

0/50 (0%)

0/50

0/50 (0%)

0/50

0/50 (0%)

(0%)

(0%)

(0%)

0/50 (0%)1/50 (2%)

**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 1/50 (2%) Mean 2% SD 0%

#Skin:

#Skin:

Osteosarcoma

0/50 (0%)0/50 (0%)

Mean 0% **Overall Incidence** Total 0/50 (0%) SD 0% Total 0/50 (0%)

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Neurofibroma or Schwannoma benign

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1 Length of Study: CHRONIC Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

**Page:** 83

			Male				Female	
#Skin: Sarcoma								
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
Skin: Schwannoma Benign		0/50 /00/				0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Schwannoma Malignant								
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin:		Paroinoma Basosquamo	ous Tumor (malignan	t or NOS).				
Squamous Cell Carcinoma or Carcinoma	, Basai Celi C		ac ramer (mangnan			0/50 (0%)		
or Carcinoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
or Carcinoma  Overall Incidence  *Skin:  Squamous Cell Papilloma	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		0/50 (0%)	Mean 0%	SD 0%
or Carcinoma  Overall Incidence  Skin:  Squamous Cell Papilloma	Total	0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		0/50 (0%)		
or Carcinoma  Overall Incidence  Skin:  Squamous Cell Papilloma	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		0/50 (0%)	Mean 0% Mean 0%	SD 0% SD 0%
or Carcinoma  Overall Incidence  Skin: Squamous Cell Papilloma  Overall Incidence	Total Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		0/50 (0%)		
or Carcinoma  Overall Incidence  Skin: Squamous Cell Papilloma  Overall Incidence  Skin:	Total Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%		0/50 (0%)		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

**Page:** 84

Report Date: 06/05/2013

SD 0%

Mean 0%

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

			Male				Female	
#Skin:								
Squamous Cell Papilloma	, Papilloma, S		a or Keratoacanthon	na		2(52 (524)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
		0/50 (0%)			10tai	0/30 (0%)	Wearr 0%	30 0%
#Skin:								
Squamous Cell Papilloma	, Papilloma, o					0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
		` '				0/50 (0%)	Wearr 0%	3D 0%
#Skin: Sebaceous Gland:								
Adenoma						- / / / /		
Occupation of James	T-1-1	0/50 (0%)	M 00/	00.00/	T-1-1	0/50 (0%)	Marana 00/	OD 00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland:								
Carcinoma or Adenoma								
Occupation of James	T-1-1	0/50 (0%)	Maran 00/	00.00/	T-1-1	0/50 (0%)	Marana 00/	00.00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Spinal Cord:								
Hemangiosarcoma								
		0/50 (0%)		05 00/		0/50 (0%)		05.00/
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Spleen:								
Hemangioma								
		0/50 (0%)				0/50 (0%)		

SD 0%

Total

0/50 (0%)

Total

0/50 (0%)

Mean 0%

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

**Page:** 85

				Male				Female	
*Spleen: Hemangiosarcoma									
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
*Spleen: Mast Cell Tumor Malignant									
mast con rame, manghant		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Spleen: Plasma Cell Tumor Malignan									
_		0/50	(0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach:			•••••						
Squamous Cell Carcinoma o	r Papilloma		(224)						
Occupati la si dan sa	T-1-1	0/50	(0%)	M 00/	OD 00/	T-1-1	0/50 (0%)	M 00/	OD 00/
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Papilloma									
		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Page: 86

(0%)

Mean 0%

SD 0%

0/46

0/46 (0%)

Total

Report Date: 06/05/2013

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1 Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC									
			Male				Female		
#Stomach, Glandular: Adenoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Stomach, Glandular: Carcinoma	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Stomach, Glandular: Carcinoma or Adenoma Overall Incidence		, ,			Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Testes: Adenoma Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%					
*Testes: Hemangioma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%					
*Thymus: Neoplasm NOS									

SD 0%

Total

(0%)

Mean 0%

0/44

0/44 (0%)

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Page: 87

		Male Female						
*Thymus: Thymoma Benign Overall Incidence	Total	0/44 (0%) 0/44 (0%)	Mean 0%	SD 0%	Total	0/46 (0%) 0/46 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant		0/44 (0%)				0/46 (0%)		
Overall Incidence	Total	0/44 (0%)	Mean 0%	SD 0%	Total	0/46 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Maligna	ant, NOS	0/44 (0%)				0/46 (0%)		
Overall Incidence	Total	0/44 (0%)	Mean 0%	SD 0%	Total	0/46 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		0/49 (0%)				0/50 (0%)		
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Ce Adenoma	HI:	1/49 (2%)				0/50 (0%)		
Overall Incidence	Total	1/49 (2.04%)	Mean 2.04%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 88

Report Date: 06/05/2013

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Thyroid Gland: Follicular Cell Carcinoma	:							
		1/49 (2%)				0/50 (0%)		
Overall Incidence	Total	1/49 (2.04%)	Mean 2.04%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell Carcinoma or Adenoma		2/49 (4%)				0/50 (0%)		
Overall Incidence	Total	2/49 (4.08%)	Mean 4.08%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tissue NOS: Fibrosarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tissue NOS: Hemangiosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tissue NOS: Plasma Cell Tumor Malignar								
		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Tissue NOS: Sarcoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Page: 89

				Male			Female           Total         0/50 (0%)         Mean 0%         SD 0%           Total         0/50 (0%)         Mean 0%         SD 0%		
#Tongue: Fibroma		1/50	(2%)				0/50 (0%)		
Overall Incidence	Total	1/50 (2%)		Mean 2%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma	or Papilloma								
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%
#Tongue: Squamous Cell Papilloma		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	` ,	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%
#Tooth: Odontoma		0/50	(0%)				' '		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Urethra: Hemangiosarcoma									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	, ,	Mean 0%	SD 0%
*Urinary Bladder: Hemangiosarcoma		0/50	(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	` '	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

**Page:** 90

Report Date: 06/05/2013

SD 0%

Mean 0%

Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1 Length of Study: CHRONIC Tumor Incidence for Selected Control Animal Groups Route: GAVAGE

Vehicle: METHYLCELLULOSE

			Male				Female	
*Urinary Bladder: Plasma Cell Tumor Ma	alignant							
	· ·	0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Uterus: Adenoma								
						0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Carcinoma								
						0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus: Hemangiosarcoma								
riemangiosarooma						0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus:								
Leiomyoma								
						0/50 (0%)		
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%
#Uterus:			• • • • • • • • • • • • • • • • • • • •					
Leiomyosarcoma								
-						0/50 (0%)		

Total

0/50 (0%)

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: METHYLCELLULOSE

**Page:** 91

			Male				Female	
#Uterus: Polyp Stromal								
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Uterus: Sarcoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Sarcoma Stromal								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Uterus: Sarcoma Stromal or Pol	lyp Stromal					4/50 (001)		
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Vagina: Liposarcoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

**Page:** 92

		Male					Female	
#Zymbal's Gland: Carcinoma or Adenoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

**Page:** 93

Report Date: 06/05/2013

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Study Summary**

Vehicle: WATER

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Columbus Laboratory Battelle Columbus Laboratory	052000506 052020304	02/10/04 07/10/07	730 730	50(1) 50(1)	32(691) 33(694)	51.1 52.6	Ginseng Green tea extract
					Female		
Battelle Columbus Laboratory Battelle Columbus Laboratory	052000506 052020304	02/09/04 07/09/07	729 729	50(5) 50(5)	38(711) 34(665)	63.9 62.9	Ginseng Green tea extract

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Page: 94
Report Date: 06/9

			Male		15/50 (30%) 18/50 (36%) Total 33/100 (33%) Mean 33% SD 4.2  42/50 (84%) 29/50 (58%) Total 71/100 (71%) Mean 71% SD 18.  1/50 (2%) 0/50 (0%) Total 1/100 (1%) Mean 1% SD 1.4			Female			
#All Organs: Benign Tumors											
_		38/50 (76%)	43/50 (86%)			33/50 (66%)	20/50 (40%)				
Overall Incidence	Total	81/100 (81%)	Mean 81%	SD 7.07%	Total	53/100 (53%)	Mean 53%	SD 18.38%			
#All Organs: Malignant Tumors											
		26/50 (52%)	28/50 (56%)			15/50 (30%)	18/50 (36%)				
Overall Incidence	Total	54/100 (54%)	Mean 54%	SD 2.83%	Total	33/100 (33%)	Mean 33%	SD 4.24%			
#All Organs: Malignant and Benign Tu	umors	40/50 (000/)	40/50 (00%)			40/50 (040/)	20/50 (500/)				
Overall Incidence	Tatal	46/50 (92%)	49/50 (98%) Mean 95%	CD 4.040/	Tatal	` '	` '	CD 40 200/			
	Total	95/100 (95%)		SD 4.24%		, ,					
#All Organs: Hemangioma		1/50 (2%)	2/50 (4%)			1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%		1/100 (1%)	Mean 1%	SD 1.41%			
#All Organs: Hemangiosarcoma											
		4/50 (8%)	5/50 (10%)			` '	` '				
Overall Incidence	Total	9/100 (9%)	Mean 9%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 2.83%			
#All Organs: Hemangiosarcoma or He	emangioma										
		5/50 (10%)	7/50 (14%)			` '	` '				
Overall Incidence	Total	12/100 (12%)	Mean 12%	SD 2.83%	Total	3/100 (3%)	Mean 3%	SD 1.41%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 95

			Male			0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0%		
#All Organs: Histiocytic Sarcoma								
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	` '	` ,	SD 0%
			ivican 170		10tai			
#All Organs: Malignant Lymphoma: Histic	ocytic, Lym			I Туре				
		4/50 (8%)	4/50 (8%)			` ,	` '	
Overall Incidence	Total	8/100 (8%)	Mean 8%	SD 0%		` '		SD 2.83%
#All Organs: Mesothelioma: Benign								
		0/50 (0%)	0/50 (0%)			` '	` ,	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		0/100 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Benign, Mali						0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		0/100 (0%)	Mean 0%	
#All Organs: Mesothelioma: Malignant								
O	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	` ,	` ,	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	ı otaı	0/100 (0%)	iviean u%	SD 0%
#All Organs: Osteoma		0/50 (00/)	0/50 (00)			0/50 (00/)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 00/	Total	` '	` ,	SD 00/
Overall incidence	Total	0/100 (0%)	iviean 0%	SD 0%	างเลเ	0/100 (0%)	Weari 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

**Page:** 96

			Male			Female			
#All Organs: Osteosarcoma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#All Organs: Osteosarcoma or Osteor	ma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
*Adrenal Cortex: Adenoma									
Overall Incidence	Total	1/50 (2%) 2/99 (2.02%)	1/49 (2%) Mean 2.02%	SD 0.03%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	
*Adrenal Cortex: Plasma Cell Tumor Malig	gnant	0/50 (00/)	0/40 (00/)			0/50 (0%)	0/40 (00/)		
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	
*Adrenal Medulla: Pheochromocytoma Ben									
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/99 (1.01%)	0/49 (0%) Mean 1%	SD 1.41%	
*Adrenal Medulla: Pheochromocytoma Mali	ignant								
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 97

			Male				Female				
*Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS  0/50 (0%) 0/49 (0%)  1/50 (2%) 0/49 (0%)											
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1%	SD 1.41%			
#Blood Vessel: Hemangioma											
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
*Bone Marrow: Hemangioma		0/50 (00/)									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
*Bone Marrow: Hemangiosarcoma		0/50 (0%)	1/50 (2%)			0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%			
*Bone Marrow: Mast Cell Tumor Malignant											
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
*Bone Marrow: Plasma Cell Tumor Malignar											
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 98

			Male			0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0%  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0%			Female			
*Bone Marrow: Sarcoma				SD 0%         Total         0/50 (0%) 0/50 (0%) Mean 0%           SD 0%         Total         0/50 (0%) 0/50 (0%) Mean 0%           SD 0%         Total         0/100 (0%) Mean 0%           SD 0%         Total         0/50 (0%) 0/50 (0%) Mean 0%           SD 0%         Total         0/100 (0%) Mean 0%           SD 0%         Total         0/50 (0%) 0/50 (0%) Mean 0%								
		0/50 (0%)	0/50 (0%)			` '	(/					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Bone: Fibroma												
		0/50 (0%)	0/50 (0%)			` ,	` '					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Bone: Hemangiosarcoma			- /									
Occupation of the second	T-1-1	0/50 (0%)	0/50 (0%)	00.00/	T-1-1	, ,	` '	OD 00/				
Overall Incidence	Total	0/100 (0%)	Mean 0%			0/100 (0%)	wean 0%	SD 0%				
#Bone: Osteoma		0/50 (001)	2/52 (221)			0(70 (00))	(00)					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%			0/100 (0%)	Mean 0%					
#Bone: Osteosarcoma												
		0/50 (0%)	0/50 (0%)			, ,	` '					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Bone: Osteosarcoma or Osteoma		0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)					
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%				
	Total	0/100 (0%)	Mean 0%		Total	0/100 (0%)						

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1 Length of Study: CHRONIC Tumor Incidence for Selected Control Animal Groups Route: GAVAGE Vehicle: WATER

**Page**: 99

			Male				Female	
#Bone: Sarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Granular Cell Tumor Ben	nign	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Meningioma Benign						0/50 (00/)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Meningioma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Meningioma: Benign, Ma	llignant, NOS	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma Maliç	gnant	0/50 (00/)	0/50 (00)			0/50 (001)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 100

13

Report	Date:	06/	05/	20	1
--------	-------	-----	-----	----	---

			Male				Female	
*Brain: Oligodendroglioma, Glion	na, or Astrocy	rtoma						
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Schwannoma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangioma		0/50 (0%)	0/50 (00/)		••••••	0/50 (00/)	0/40 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Coagulating Gland: Granular Cell Tumor								
		0/50 (0%)	0/50 (0%)	05.00		0/50 (0%)	0/50 (0%)	05.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Coagulating Gland: Sarcoma		0/50 (09/)	4/50 (20/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 101

			Male				Female	
#Esophagus: Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Eye: Melanoma Malignant								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Harderian Gland: Adenoma								
		11/50 (22%)	7/50 (14%)			7/50 (14%)	2/50 (4%)	
Overall Incidence	Total	18/100 (18%)	Mean 18%	SD 5.66%	Total	9/100 (9%)	Mean 9%	SD 7.07%
#Harderian Gland: Carcinoma						-4		
		1/50 (2%)	1/50 (2%)	05.00/		0/50 (0%)	2/50 (4%)	00.000/
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 2.83%
#Harderian Gland: Carcinoma or Adenoma								
		12/50 (24%)	8/50 (16%)			7/50 (14%)	4/50 (8%)	
Overall Incidence	Total	20/100 (20%)	Mean 20%	SD 5.66%	Total	11/100 (11%)	Mean 11%	SD 4.24%
*Heart: Hemangiosarcoma								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 102

			Male				Female	
#Intestine Large: Cecum: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Carcinoma or Adenoma								
Occupation of the second	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Leiomyoma								
Occupation of James	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rect Leiomyosarcoma	um:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 103

		Male				Female	
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
	` '	, ,			` ,	` '	
	, ,				, ,		SD 0%
	0/50 (001)	0/50 (00/)			0/50 (00/)	0/50 (00)	
Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Total	` '	` ,	SD 0%	Total	` ,	` '	SD 0%
	Total  Total	Total 0/100 (0%)  0/50 (0%)  Total 0/100 (0%)  0/50 (0%)  Total 0/100 (0%)  Total 0/50 (0%)  Total 0/100 (0%)  Total 0/50 (0%)  Total 0/50 (0%)  Total 0/100 (0%)	Total 0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0%  Total 0/100 (0%) 0/50 (0%)  Total 0/100 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0%	Total 0/100 (0%) Mean 0% SD 0%  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0%  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0%  Total 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0%  Total 0/50 (0%) 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0%  Total 0/50 (0%) 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0%	Total         0/100 (0%)         Mean 0%         SD 0%         Total           0/50 (0%)         0/50 (0%)         0/50 (0%)         Total           Total         0/100 (0%)         0/50 (0%)         SD 0%         Total           Total         0/100 (0%)         0/50 (0%)         SD 0%         Total           Total         0/100 (0%)         0/50 (0%)         SD 0%         Total           Total         0/50 (0%)         0/50 (0%)         SD 0%         Total           Total         0/100 (0%)         0/50 (0%)         SD 0%         Total           Total         0/100 (0%)         0/50 (0%)         SD 0%         Total	Total         0/100 (0%)         Mean 0%         SD 0%         Total         0/100 (0%)           0/50 (0%)         0/50 (0%)         0/50 (0%)         0/50 (0%)           Total         0/100 (0%)         Mean 0%         SD 0%         Total         0/100 (0%)           Total         0/50 (0%)         0/50 (0%)         0/50 (0%)         0/100 (0%)         0/50 (0%)           Total         0/100 (0%)         Mean 0%         SD 0%         Total         0/100 (0%)           Total         0/100 (0%)         0/50 (0%)         0/50 (0%)         0/50 (0%)           Total         0/100 (0%)         Mean 0%         SD 0%         Total         0/100 (0%)           Total         0/100 (0%)         Mean 0%         SD 0%         Total         0/100 (0%)	Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  O/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  O/50 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 104

			Male				Female	
#Intestine Small: Ileum: Polyp Adenomatous								
		0/50 (0%)	0/50 (0%)	05.00		0/50 (0%)	0/50 (0%)	05.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Carcinoma								
		0/50 (0%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	22 22/		0/50 (0%)	0/50 (0%)	00.007
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Intestine Small: Site Unspec Adenoma	cified:							
	<b>.</b>	0/50 (0%)	0/50 (0%)	00.00/	<b>T</b>	0/50 (0%)	0/50 (0%)	05.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 105

			Male				Female	
#Intestine Small: Site Unsp	pecified:							
		0/50 (0%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp Carcinoma or Adenoma								
		0/50 (0%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Intestine Small: Site Unsp Polyp Adenomatous	pecified:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma								
		1/50 (2%)	1/50 (2%)			1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 106

			Male				Female	
*Islets, Pancreatic: Carcinoma								
		1/50 (2%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma								
		2/50 (4%)	2/50 (4%)			1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 0%
*Kidney: Pelvis and Transitio Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Pelvis and Transitio Carcinoma or Adenoma		m:				- ()	2(-2)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Adenoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma		(Jan (Jan))				0.000	(00)	
		1/50 (2%)	2/50 (4%)	<b>25</b>		0/50 (0%)	0/50 (0%)	05 00/
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 107

			Male				Female	
*Kidney: Renal Tubule: Carcinoma or Adenoma		1/50 (2%)	3/50 (6%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Kidney: Renal Tubule: Plasma Cell Tumor Maligna	ant	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
'Kidney: Renal Tubule: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Liver: Hemangioma								
Overall Incidence	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 108

			Male				Female	
*Liver: Hemangiosarcoma								
		2/50 (4%)	3/50 (6%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Liver: Hepatoblastoma								
		1/50 (2%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Adenoma		24/50 (690/)	25/50 /709/\			24/50 (420()	42/50 (249/)	
Overall Incidence	Total	34/50 (68%) 69/100 (69%)	35/50 (70%) Mean 69%	SD 1.41%	Total	21/50 (42%) 33/100 (33%)	12/50 (24%) Mean 33%	SD 12.73%
	10tai		······································					
*Liver: Hepatocellular Carcinoma								
Occupation of the second	T-1-1	14/50 (28%)	15/50 (30%)	OD 4 440/	T-1-1	2/50 (4%)	5/50 (10%)	00 4 0 4 0 4 0 4 0 4
Overall Incidence	Total	29/100 (29%)	Mean 29%	SD 1.41%	Total	7/100 (7%)	Mean 7%	SD 4.24%
*Liver: Hepatocellular Carcinoma o	or Hepatobl	astoma						
-	-	14/50 (28%)	17/50 (34%)			2/50 (4%)	5/50 (10%)	
Overall Incidence	Total	31/100 (31%)	Mean 31%	SD 4.24%	Total	7/100 (7%)	Mean 7%	SD 4.24%
*Liver: Hepatocellular Carcinoma o	or Hepatoce		40/50 (00%)			00/50 (400/)	44/50 (000)	
Overall Incidence	Total	39/50 (78%)	40/50 (80%)	SD 1.410/	Total	23/50 (46%)	14/50 (28%)	CD 12 720/
Overall Incidence	Total	79/100 (79%)	Mean 79%	SD 1.41%	Total	37/100 (37%)	Mean 37%	SD 12.73%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 109

			Male				Female					
*Liver: Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma 39/50 (78%) 40/50 (80%) 23/50 (46%) 14/50 (28%)												
Overall Incidence	Total	79/100 (79%)	Mean 79%	SD 1.41%	Total	37/100 (37%)	Mean 37%	SD 12.73%				
*Liver: Hepatocholangiocarcinom												
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Liver: Hepatocholangioma												
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Liver: Ito Cell Tumor Benign		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Liver: Mast Cell Tumor Malignan			0/50 (0%)			0/50 (0%)						
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Liver: Plasma Cell Tumor Malign	ant	0/50 (00)	0/50 (000)			0/50 (00)	0/50 /00/					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 110

			Male				Female					
*Liver: Sarcoma 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Lung: Alveolar/Bronchiolar Ad	denoma											
		9/50 (18%)	12/50 (24%)			6/50 (12%)	5/50 (10%)					
Overall Incidence	Total	21/100 (21%)	Mean 21%	SD 4.24%	Total	11/100 (11%)	Mean 11%	SD 1.41%				
*Lung: Alveolar/Bronchiolar Ca	arcinoma	2/52 (694)	0/50 /40/			4/50 (001)	4/50 (00/)					
Overall Incidence	Total	3/50 (6%) 5/100 (5%)	2/50 (4%) Mean 5%	SD 1.41%	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%				
*Lung: Alveolar/Bronchiolar Ca Overall Incidence	arcinoma or Alv Total	eolar/Bronchiolar Adenor 12/50 (24%) 26/100 (26%)	<b>na</b> 14/50 (28%) Mean 26%	SD 2.83%	Total	7/50 (14%) 13/100 (13%)	6/50 (12%) Mean 13%	SD 1.41%				
*Lung: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Lung: Plasma Cell Tumor Mali	ignant	0/50 (00)	0/50 /00/			0/50 (00/)	0/50 (00)					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
		0/100 (0%)				` ,	IVICALI U%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 111

		Male				Female							
#Lymph Node: Plasma Cell Tumor Malignant													
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)							
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%						
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)							
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%						
<b>-</b>	` '	` '	00.00/	<b>-</b>	` ,	` '	00.00/						
l otal	0/100 (0%)	Mean 0%	SD 0%	ı otal	0/100 (0%)	Mean 0%	SD 0%						
nt	1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)							
Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%						
nant													
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)							
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%						
nt	0/50 (0%)	0/50 (00/)			0/50 (09/\	0/50 (09/)							
Total	` '	` ,	SD 0%	Total	` '	` '	SD 0%						
	Total  Total  Total  Total  Total  Total	0/50 (0%) Total 0/100 (0%)  0/50 (0%)  Total 0/100 (0%)  Total 0/50 (0%)  Total 0/100 (0%)  1/50 (2%)  Total 1/100 (1%)  nant  0/50 (0%)  Total 0/100 (0%)	Total 0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0%  1/50 (2%) 0/50 (0%)  Total 1/100 (1%) Mean 1%  nant  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0%	Total 0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD 0%     0/50 (0%) 0/50 (0%)   Total 0/100 (0%) Mean 0% SD 0%    Total 0/50 (0%) 0/50 (0%)   Total 0/100 (0%) Mean 0% SD 0%    1/50 (2%) 0/50 (0%)   Total 1/100 (1%) Mean 1% SD 1.41%    1/50 (2%) 0/50 (0%)   Total 0/100 (0%) Mean 1% SD 1.41%    Total 0/100 (0%) Mean 0% SD 0%	Total 0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total  1/50 (2%) 0/50 (0%)  Total 1/100 (1%) Mean 1% SD 1.41% Total  nant  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total	Total 0/50 (0%) 0/50 (0%) SD 0% Total 0/100 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  Total 0/100 (0%) 0/50 (0%) SD 0% Total 0/100 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  Total 0/100 (0%) Mean 1% SD 1.41% Total 0/100 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)	Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) 0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%  Total 0/100 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  Total 1/50 (2%) 0/50 (0%) SD 1.41% Total 0/100 (0%) Mean 0%  Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) 0/50 (0%) 0/50 (0%)						

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 112

			Male				Female	
#Lymph Node, Mesenteric: Hemangiosarcoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Plasma Cell Tumor Malignar	nt							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoma								
		0/50 (0%)	0/50 (0%)	25 22/		1/50 (2%)	0/50 (0%)	05
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Mammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	25 22/		0/50 (0%)	0/50 (0%)	05.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Mammary Gland: Fibroadenoma		- (ac)	(05.1)					
Overall Insidence	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 113

			Male				Female						
#Mammary Gland: Fibroma, Fibroadenoma or Adenoma													
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)						
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%					
#Mammary Gland: Fibroma, Fibroadenoma	a, Carcinoma, or	Adenoma											
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)						
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%					
#Mesentery: Hemangioma		0/50 (0%)	0/50 (09/)			0/50 (00/)	0/50 (00/)						
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%					
		, ,											
#Mesentery: Hemangiosarcoma							- ()						
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%					
	10tai	0/100 (0%)			10tai	0/100 (0%)	Mean 0%	3D 0%					
#Mesentery: Lipoma													
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)						
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%					
#Mesentery: Sarcoma		- (ac)											
Overell healdenes	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%					

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 114

			Male				Female	
*Nose: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/48 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/98 (1.02%)	Mean 1.04%	SD 1.47%
*Nose: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Papilloma Squamous o	sa, Tongue, Phary	ynx, Tooth, Gingiva):						
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcine	sa, Tongue, Phary							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos	sa, Tongue, Phary		0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Oral Mucosa: Squamous Cell Carcin	oma	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall incidence	างเลเ	0/100 (0%)	iviean 0%	SD 0%	าบเลเ	0/100 (0%)	Mean 0%	3D 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 115

	Male			Female	
*Ovary: Choriocarcinoma			2/22 (221)	2/52 (22)	
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Cystadenocarcinoma					
Overall Incidence		Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
*Ovary: Cystadenoma			<b>-</b> (-)	0.75	
Overall Incidence		Total	7/50 (14%) 10/100 (10%)	3/50 (6%) Mean 10%	SD 5.66%
*Ovary: Granulosa Cell Tumor Benign			(201)	(201)	
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Hemangioma					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

**Page:** 116

	Male			Female	
*Ovary: Hemangiosarcoma			2(72)	(201)	
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Luteoma					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Plasma Cell Tumor Malignant			0/50 (00/)	0/50 (00())	
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Sarcoma					
Overall Incidence		Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
*Ovary: Teratoma Benign					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Teratoma Malignant					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 117

			Male				Female	
*Ovary: Tubulostromal Adenoma	a							
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Yolk Sac Carcinoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pituitary Gland: Pars Dist		fied Site:				•••••		
Overall Incidence	Total	1/50 (2%) 2/99 (2.02%)	1/49 (2%) Mean 2.02%	SD 0.03%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
*Pituitary Gland: Pars Dist		fied Site:						
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 118

			Male				Female					
*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma												
		1/50 (2%)	1/49 (2%)			1/50 (2%)	0/50 (0%)					
Overall Incidence	Total	2/99 (2.02%)	Mean 2.02%	SD 0.03%	Total	1/100 (1%)	Mean 1%	SD 1.41%				
*Pituitary Gland: Pars Inte Adenoma	ermedia:											
		0/50 (0%)	0/49 (0%)			1/50 (2%)	0/50 (0%)					
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%				
*Pituitary Gland: Pars Inte Carcinoma or Adenoma												
O	T-1-1	0/50 (0%)	0/49 (0%)	OD 00/	T-1-1	1/50 (2%)	0/50 (0%)	00 4 440/				
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%				
*Salivary Glands: Adenoma												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Salivary Glands: Carcinoma or Adenoma	a											
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Salivary Glands: Hemangiosarcoma			0.000			0.50						
O !!   ! .	Taral	0/50 (0%)	0/50 (0%)	OD 00/	Tatal	0/50 (0%)	0/50 (0%)	OD 00/				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 119

		Male				Female	
nt							
	1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Total	, ,			Total	0/100 (0%)	Mean 0%	SD 0%
					0(50 (001)	0/50 (00/)	
Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
	0/50 (0%)	0/50 (0%)					
Total	0/50 (0%)	Mean 0%	SD 0%				
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
	0/50 (0%)	0/50 (0%)			0/50 (0%)	2/50 (4%)	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 2.83%
habdomyoma	(20)				2(-2)		
Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%
	Total  Total  Total  Total  habdomyoma	1/50 (2%) Total 1/100 (1%)  0/50 (0%) Total 0/100 (0%)  Total 0/50 (0%)  Total 0/100 (0%)  Total 0/50 (0%)  Total 0/100 (0%)  Total 0/50 (0%)  Total 0/100 (0%)  habdomyoma  0/50 (0%)	1/50 (2%) 0/50 (0%) Total 1/100 (1%) Mean 1%  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%  1 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%  1 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%  1 0/50 (0%) Mean 0%  1 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%  1 0/50 (0%) 0/50 (0%)  1 0/50 (0%) 0/50 (0%)  1 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%) Total 1/100 (1%) Mean 1% SD 1.41%  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0%  Total 0/100 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0%  Total 0/100 (0%) Mean 0% SD 0%	Total 1/50 (2%) 0/50 (0%) Total 1/100 (1%) Mean 1% SD 1.41% Total  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0%  Total 0/50 (0%) Mean 0% SD 0%  Total 0/50 (0%) Mean 0% SD 0%  Total 0/50 (0%) 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0%  Total 0/50 (0%) 0/50 (0%)	tt  1/50 (2%) 0/50 (0%) Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%)  0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  Total 0/100 (0%) Mean 0% SD 0%  Total 0/100 (0%)	Total 1/50 (2%) 0/50 (0%) Mean 1% SD 1.41% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) 0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD 0%  Total 0/100 (0%) Mean 0%  SD 0%  Total 0/100 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0%  SD 0%  Total 0/100 (0%) 0/50 (0%) Mean 0%  SD 0%  Total 0/100 (0%) 0/50 (0%) 0/50 (4%)  Mean 2%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE Strain: B6C3F1

#### **Toxicology Data Management System**

Page: 120

Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups Contract/Lab: All Laboratories

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: WATER

Male **Female #Skeletal Muscle:** Sarcoma 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%) Mean 0% SD 0% #Skin: **Basal Cell Carcinoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% Total #Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% Total ...... #Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/100 (0%) Overall Incidence Total 0/100 (0%) Mean 0% SD 0% Total Mean 0% SD 0% #Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma 0/50 (0%)0/50 (0%)0/50 0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma (2%)0/50 (0%)4/50 (8%)0/50 (0%)SD 1.41% SD 5.66% **Overall Incidence** Total 1/100 (1%) Mean 1% Total 4/100 (4%) Mean 4%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 121

			Male				Female					
#Skin: Fibrosarcoma												
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	3/50 (6%) 3/100 (3%)	0/50 (0%) Mean 3%	SD 4.24%				
#Skin:	M	as Filosopa Histia automa										
Fibrosarcoma, Sarcoma	, wyxosarcoma	, or Fibrous Histiocytoma 1/50 (2%)	0/50 (0%)			4/50 (8%)	0/50 (0%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	4/100 (4%)	Mean 4%	SD 5.66%				
#Skin: Fibrous Histiocytoma												
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%				
#Skin: Granular Cell Tumor Bel	nign	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Skin: Hemangioma												
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Skin: Hemangiosarcoma		0/50 (00:)	0/50 (05)			0(50 (00))	0/50 (00/)					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 122

			Male				Female	
#Skin: Keratoacanthoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
#Skin: Lipoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Liposarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Mast Cell Tumor Benign						0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Mast Cell Tumor Malignant								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Melanoma Benign		0/50 (00/)	0/50 (00/)			0/50 /00/	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 123

(0%) 0/50 Mear (0%) 0/50 Mear (0%) 0/50 Mear	SD 0% Total  SD 0% Total  SD 0% Total	0/50 (0%) 0/50 (0%) 0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%) 0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%) 0/100 (0%) Mean 0%	SD 0% SD 0% SD 0%
(0%) 0/50 Mear	SD 0% Total	0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%)  0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%)	SD 0%
(0%) 0/50 Mear	SD 0% Total	0/50 (0%) 0/50 (0%) 0/100 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	SD 0%
Mear (0%) 0/50		0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%)	
Mear (0%) 0/50		0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%)	
(0%) 0/50		0/50 (0%) 0/50 (0%)	
` '	SD 0% Total	. , , , , , , , , , , , , , , , , , , ,	SD 0%
` '	SD 0% Total	. , , , , , , , , , , , , , , , , , , ,	SD 0%
<b>6)</b> (2%) 0/50		2/50 (4%) 0/50 (0%)	
Mear	SD 1.41% Total	2/100 (2%) Mean 2%	SD 2.83%
enign, malignant or		2/50 (4%) 0/50 (0%)	
` '	SD 1.41% Total	2/100 (2%) Mean 2%	SD 2.83%
		0/50 (00() 0/50 (00()	
(00()		( )	SD 0%
	(2%) 0/50 (0%) Mean 1%  (0%) 0/50 (0%)	(2%) 0/50 (0%) Mean 1% SD 1.41% Total  (0%) 0/50 (0%)	(2%) 0/50 (0%) 2/50 (4%) 0/50 (0%)  Mean 1% SD 1.41% Total 2/100 (2%) Mean 2%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 124

			Male			Female			
#Skin: Sarcoma		200	2(72 (22))			2(72)	0.50		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Skin: Schwannoma Benign		0/50 (00/)	0/50 (00)			0(50 (00))	0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
Skin: Schwannoma Malignant									
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%	
#Skin: Squamous Cell Carcinom or Carcinoma	a, Basal Cell (	•		or NOS),		0/50 (00/)	0/50 (09/)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
Skin: Squamous Cell Papilloma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
Skin:	or Papilloma					0/50 (0%)	0/50 (0%)		
Squamous Cen Fapinoma		0/50 (0%)	0/50 (0%)						

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 125

			Male				Female	
#Skin: Squamous Cell Papilloma	a, Papilloma, S	-		ı				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma	a, Papilloma, o	r Keratoacanthoma					•••••	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Spinal Cord: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Spleen: Hemangioma			(00)			(20)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 126

			Male				Female	
*Spleen: Hemangiosarcoma								
_		1/50 (2%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Spleen: Mast Cell Tumor Malignan	t							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Spleen: Plasma Cell Tumor Malign	ant	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma	1	0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Stomach, Forestomach: Squamous Cell Carcinoma			0/50 (0%)			0/50 (0%)	2/50 (4%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 2.83%
#Stomach, Forestomach: Squamous Cell Papilloma		1/50 (2%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/100 (1%)	0/30 (0%) Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 127

			Male				Female	
#Stomach, Glandular: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Testes: Adenoma  Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%				
·····		` '						
*Testes: Hemangioma								
		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
*Thymus: Neoplasm NOS								
		0/47 (0%)	0/44 (0%)	00.00		0/48 (0%)	0/47 (0%)	25.00/
Overall Incidence	Total	0/91 (0%)	Mean 0%	SD 0%	Total	0/95 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 128

			Male				Female	
*Thymus: Thymoma Benign		0/47 (0%)	0/44 (0%)			0/48 (0%)	0/47 (0%)	
Overall Incidence	Total	0/91 (0%)	Mean 0%	SD 0%	Total	0/95 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant		0/47 (00/)	2/44 (22/)			0/40 (00/)	0/47 (00/)	
Overall Incidence	Total	0/47 (0%) 0/91 (0%)	0/44 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/95 (0%)	0/47 (0%) Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Maligna	ant, NOS	0/47 (0%)	0/44 (0%)			0/48 (0%)	0/47 (0%)	
Overall Incidence	Total	0/91 (0%)	Mean 0%	SD 0%	Total	0/95 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma						0/40 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma						•••••		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Thyroid Gland: Follicular Ce Adenoma								
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 129

			Male				Female	
*Thyroid Gland: Follicular Ce Carcinoma	ell:							
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Ce Carcinoma or Adenoma								
		1/50 (2%)	1/50 (2%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Tissue NOS: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tissue NOS: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	05 00/		0/50 (0%)	0/50 (0%)	<b>05</b>
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tissue NOS: Plasma Cell Tumor Maligna	ant							
_		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tissue NOS: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 130

			Male				Female	
#Tongue: Fibroma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinom								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tooth: Odontoma		0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Urethra: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 131

			Male			Female			
*Urinary Bladder: Plasma Cell Tumor Maligi	nant								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%	
#Uterus: Adenoma									
						0/50 (0%)	0/50 (0%)		
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%	
#Uterus: Carcinoma									
						0/50 (0%)	0/50 (0%)		
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%	
#Uterus: Hemangiosarcoma						0/50 (00()	0/50 (00/)		
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Uterus: Leiomyoma									
•						0/50 (0%)	0/50 (0%)		
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%	
#Uterus: Leiomyosarcoma									
•						0/50 (0%)	0/50 (0%)		
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 132

		Male				Female	
#Uterus: Polyp Stromal							
Overall Incidence				Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%
#Uterus: Sarcoma							
Overall Incidence				Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Sarcoma Stromal							
Overall Incidence				Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Sarcoma Stromal or Polyp Stromal					0/50 (00/)	0/50 (400)	
Overall Incidence				Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%
#Vagina: Liposarcoma							•••••
Overall Incidence				Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma					(20)		
Overall Incidence Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 133

			Male				Female	
#Zymbal's Gland: Carcinoma or Adenoma		2/22 (221)	2(72 (224)			2(52)	0.50	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

**Page:** 134

Report Date: 06/05/2013

Species: MICE Strain: B6C3F1 Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

### **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Northwest	052001106	07/21/03	729	50(5)	37(689)	53.4	1-Bromopropane
Battelle Northwest	056031106	05/15/06	729	50(5)	39(715)	54.3	Cobalt
Battelle Northwest	059901706	08/18/03	729	50(5)	31(686)	53.8	Diethylamine
Battelle Northwest	052051504	05/05/08	729	50(5)	39(709)	52.6	Metal working fluids (CIMSTAR 3800)
Battelle Northwest	059302506	06/23/03	729	50(5)	36(695)	52.9	Tetralin
Battelle Northwest	052030306	06/20/05	729	50(5)	29(680)	53.1	Vinylidene chloride
					Female		
Battelle Northwest	052001106	07/21/03	731	50(5)	36(698)	61.2	1-Bromopropane
Battelle Northwest	056031106	05/15/06	731	50(5)	36(686)	66.7	Cobalt
Battelle Northwest	059901706	08/18/03	731	50(5)	32(684)	60.7	Diethylamine
Battelle Northwest	052051504	05/05/08	731	50(5)	39(696)	59.2	Metal working fluids (CIMSTAR 3800)
Battelle Northwest	059302506	06/23/03	731	50(5)	31(663)	62.1	Tetralin
Battelle Northwest	052030306	06/20/05	731	50(5)	36(687)	66.0	Vinylidene chloride

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 135

Report Date: 06/05/2013

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female
#All Organs: Benign Tumors						
-		36/50 (72%)	35/50 (70%) 33/50	(66%)	22/50 (44%)	29/50 (58%) 25/50 (50%)
		39/50 (78%)	42/50 (84%) 43/50	(86%)	26/50 (52%)	24/50 (48%) 32/50 (64%)
Overall Incidence	Total	228/300 (76%)	Mean 76% SD 8%	Total	158/300 (52.67%)	Mean 52.67% SD 7.23%
#All Organs: Malignant Tumors						
		30/50 (60%)	36/50 (72%) 36/50	(72%)	33/50 (66%)	31/50 (62%) 23/50 (46%)
		26/50 (52%)	26/50 (52%) 37/50	(74%)	30/50 (60%)	27/50 (54%) 33/50 (66%)
Overall Incidence	Total	191/300 (63.67%)	Mean 63.67% SD 10.31	I% Total	177/300 (59%)	Mean 59% SD 7.77%
#All Organs: Malignant and Benign T	umors	47/50 (94%) 46/50 (92%)	45/50 (90%) 48/50 47/50 (94%) 49/50	(96%) (98%)	42/50 (84%) 41/50 (82%)	40/50 (80%) 41/50 (82%) 40/50 (80%) 45/50 (90%)
Overall Incidence	Total	282/300 (94%)	Mean 94% SD 2.83	` '	249/300 (83%)	Mean 83% SD 3.74%
#All Organs: Hemangioma		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
		1/50 (2%)	1/50 (2%) 1/50	(2%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	3/300 (1%)	Mean 1% SD 1.19	% Total	0/300 (0%)	Mean 0% SD 0%
#All Organs: Hemangiosarcoma						
		2/50 (4%)	7/50 (14%) 7/50	(14%)	4/50 (8%)	3/50 (6%) 5/50 (10%)
• " " " "	<b>-</b>	1/50 (2%)	4/50 (8%) 2/50	(4%)	3/50 (6%)	2/50 (4%) 4/50 (8%)
Overall Incidence	Total	23/300 (7.67%)	Mean 7.67% SD 5.28	% Total	21/300 (7%)	Mean 7% SD 2.1%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

**Toxicology Data Management System** 

Page: 136

Report Date: 06/05/2013

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Strain: B6C3F1 Length of Study: CHRONIC

			Male				Female	
#All Organs: Hemangiosarcoma or Her	nangioma							
		2/50 (4%)	` ,	/50 (14%)		4/50 (8%)	3/50 (6%)	5/50 (10%)
		2/50 (4%)	, ,	/50 (6%)		3/50 (6%)	2/50 (4%)	4/50 (8%)
Overall Incidence	Total	26/300 (8.67%)		4.68%	Total	21/300 (7%)	Mean 7%	SD 2.1%
#All Organs: Histiocytic Sarcoma								
		0/50 (0%)	` ,	/50 (2%)		1/50 (2%)	1/50 (2%)	1/50 (2%)
		1/50 (2%)	` '	/50 (4%)		2/50 (4%)	2/50 (4%)	2/50 (4%)
Overall Incidence	Total	5/300 (1.67%)	Mean 1.67% SD	1.51%	Total	9/300 (3%)	Mean 3%	SD 1.1%
Overall Incidence	Total	2/50 (4%) 3/50 (6%) 15/300 (5%)	2/50 (4%) 2/	/50 (4%) /50 (4%) 1.67%	Total	17/50 (34%) 18/50 (36%) 83/300 (27.67%)	14/50 (28%) 12/50 (24%) Mean 27.67%	8/50 (16%) 14/50 (28%) SD 7.2%
#All Organs:	Total	15/300 (5%)	Mean 5% SD	1.67%	Total	83/300 (27.67%)	Mean 27.67%	SD 7.2%
Mesothelioma: Benign								
		0/50 (0%)	` ,	/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	` '	/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0% SD	0%	Total	0/300 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Benign, M	alignant, NO	S						
		0/50 (0%)	` ,	/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	` '	/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33% SD	0.82%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 137

Report Date: 06/05/2013

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#All Organs: Mesothelioma: Malignant								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
All Organs: Osteoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
All Organs: Osteosarcoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
All Organs: Osteosarcoma or Osteoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
Adrenal Cortex: Adenoma								
		4/49 (8%)	1/50 (2%)	6/50 (12%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		9/49 (18%)	2/49 (4%)	1/50 (2%)		0/49 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	23/297 (7.74%)	Mean 7.77%	SD 6.49%	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 138

			Male				Female			
*Adrenal Cortex: Plasma Cell Tumor Malignant										
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/49 (0%) 0/297 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 0/299 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
Adrenal Medulla: Pheochromocytoma Be	enign									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		3/50 (6%)	1/50 (2%)	0/50 (0%)		
		1/48 (2%)	1/47 (2%)	1/50 (2%)		1/49 (2%)	0/50 (0%)	1/50 (2%)		
Overall Incidence	Total	4/295 (1.36%)	Mean 1.37%	SD 1.06%	Total	6/299 (2.01%)	Mean 2.01%	SD 2.19%		
*Adrenal Medulla: Pheochromocytoma Ma	<b>alignant</b> Total	0/50 (0%) 0/48 (0%) 1/295 (0.34%)	0/50 (0%) 0/47 (0%) Mean 0.33%	0/50 (0%) 1/50 (2%) SD 0.82%	Total	1/50 (2%) 0/49 (0%) 2/299 (0.67%)	0/50 (0%) 0/50 (0%) Mean 0.67%	0/50 (0%) 1/50 (2%) SD 1.03%		
		1/293 (0.5470)				` ,				
*Adrenal Medulla: Pheochromocytoma: B	Benign, Complex	x, <b>Malignant, NOS</b> 1/50 (2%) 1/48 (2%)	0/50 (0%) 1/47 (2%)	0/50 (0%) 2/50 (4%)		4/50 (8%) 1/49 (2%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 2/50 (4%)		
Overall Incidence	Total	5/295 (1.69%)	Mean 1.7%	SD 1.52%	Total	8/299 (2.68%)	Mean 2.67%	SD 3.01%		
#Blood Vessel: Hemangioma										
ū		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 139

Report Date: 06/05/2013

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Bone Marrow: Hemangioma 0/48 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/300 (0%) **Overall Incidence** Total 0/298 (0%) Mean 0% SD 0% Total Mean 0% SD 0% \*Bone Marrow: Hemangiosarcoma (0%) (0%) 0/481/50 (2%)2/50 (4%)0/50 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 4/298 (1.34%) Mean 1.33% SD 1.63% Total 2/300 (0.67%) Mean 0.67% SD 1.03% \*Bone Marrow: Mast Cell Tumor Malignant 0/48 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/298 (0%) Mean 0% SD 0% Total 1/300 (0.33%) Mean 0.33% SD 0.82% \*Bone Marrow: **Plasma Cell Tumor Malignant** 0/50 0/48 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) 0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/298 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% \*Bone Marrow: Sarcoma 0/48 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/298 (0%) Mean 0% SD 0% Total 1/300 (0.33%) Mean 0.33% SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 140

Report Date: 06/05/2013

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Bone: **Fibroma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/300 (0%) **Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total Mean 0% SD 0% #Bone: Hemangiosarcoma (0%) 0/50 0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% Total 2/300 (0.67%) Mean 0.67% SD 1.03% #Bone: Osteoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% 0/300 (0%) Mean 0% SD 0% Total #Bone: Osteosarcoma 0/50 1/50 (2%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% Total 0/300 (0%) Mean 0% SD 0% #Bone: Osteosarcoma or Osteoma 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% Total 0/300 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 141

			Male				Female	
#Bone: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Brain: Granular Cell Tumor Ben	ign							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
*Brain: Meningioma Benign								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
*Brain: Meningioma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
*Brain: Meningioma: Benign, Ma	lignant, NOS							
3 ,	<u> </u>	0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Page: 142

Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female				
*Brain: Oligodendroglioma Malignant											
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			
Overall Incidence	Total	0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			
Brain: Oligodendroglioma, Gl	ioma. or Astrocy	rtoma									
g g,		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%			
Brain: Schwannoma Malignan											
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%			
Clitoral/Preputial Gland: Hemangioma											
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/46 (0%)	0/43 (0%)	0/46 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/44 (0%)	0/46 (0%)	0/45 (0%)			
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/270 (0%)	Mean 0%	SD 0%			
Clitoral/Preputial Gland: Hemangiosarcoma											
-		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/46 (0%)	0/43 (0%)	0/46 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/44 (0%)	0/46 (0%)	0/45 (0%)			
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/270 (0%)	Mean 0%	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 143

Report Date: 06/05/2013

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Coagulating Gland: Granular Cell Tumor** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/300 (0%) **Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total Mean 0% SD 0% #Coagulating Gland: Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 0/300 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% #Esophagus: **Squamous Cell Carcinoma** 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% 1/300 (0.33%) Mean 0.33% SD 0.82% Total #Eye: **Melanoma Malignant** 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% #Harderian Gland: Adenoma 7/50 (14%)6/50 (12%)4/50 (8%)3/50 (6%)3/50 (6%)3/50 (6%)7/50 (14%)2/50 (4%)7/50 (14%)2/50 (4%)1/50 (2%)1/50 (2%)**Overall Incidence** Total 33/300 (11%) Mean 11% SD 4.15% Total 13/300 (4.33%) Mean 4.33%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

## **Toxicology Data Management System**

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 144

			Male				Female	
#Harderian Gland: Carcinoma								
		3/50 (6%)	2/50 (4%)	4/50 (8%)		2/50 (4%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	5/50 (10%) 17/300 (5.67%)	3/50 (6%) Mean 5.67%	0/50 (0%) SD 3.44%	Total	0/50 (0%) 8/300 (2.67%)	1/50 (2%) Mean 2.67%	3/50 (6%) SD 2.42%
		, ,				` ,		
#Harderian Gland: Carcinoma or Adenoma								
		10/50 (20%)	8/50 (16%)	8/50 (16%)		5/50 (10%)	3/50 (6%)	5/50 (10%)
O	T-1-1	12/50 (24%)	5/50 (10%)	7/50 (14%)	T-1-1	2/50 (4%)	2/50 (4%)	4/50 (8%)
Overall Incidence	Total	50/300 (16.67%)	Mean 16.67%	SD 4.84%	Total	21/300 (7%)	Mean 7%	SD 2.76%
*Heart: Hemangiosarcoma								
-		0/50 (0%)	1/50 (2%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Intestine Large: Cecum: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

**Page:** 145

Report Date: 06/05/2013

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male		Female
#Intestine Large: Cecum: Carcinoma or Adenoma					
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%) 1/50 (2%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33% SD 0.82%	Total 1/300 (0.33%)	Mean 0.33% SD 0.82%
#Intestine Large: Cecum: Leiomyoma					
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 1/50 (2%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0% SD 0%	Total 1/300 (0.33%)	Mean 0.33% SD 0.82%
#Intestine Large: Cecum: Leiomyosarcoma					
•		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0% SD 0%	Total 0/300 (0%)	Mean 0% SD 0%
#Intestine Large: Colon/Rectu Leiomyosarcoma					
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0% SD 0%	Total 1/300 (0.33%)	Mean 0.33% SD 0.82%
#Intestine Small: Duodenum: Adenoma					
		0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
		1/50 (2%)	0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67% SD 1.03%	Total 1/300 (0.33%)	Mean 0.33% SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 146

				Male					Female	
fintestine Small: Duodenum: Carcinoma										
		0/50 (0%	,	(0%)	0/50	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%	%) 0/50	(0%)	0/50	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean	0%	SD 0%		Total	0/300 (0%)	Mean 0%	SD 0%
fintestine Small: Duodenum: Leiomyosarcoma										
		0/50 (0%	%) 0/50	(0%)	0/50	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%	%) 0/50	(0%)	0/50	(0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean		SD 0%		Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Intestine Small: Duodenum: Polyp Adenomatous										
		1/50 (29	,	(0%)	0/50	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%	%) 0/50	(0%)	0/50	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean (	).33%	SD 0.82%	%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Adenoma										
		0/50 (0%	,	(2%)	0/50	(0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%	%) 0/50	(0%)	1/50	(2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	2/300 (0.67%)	Mean (	).67%	SD 1.03%	%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Intestine Small: Ileum: Carcinoma										
		0/50 (0%	%) 0/50	(0%)	0/50	(0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%	%) 0/50	(0%)	0/50	(0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/300 (0%)	Mean	0%	SD 0%		Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 147 Report Date: 06/05/2013

			Male				Female	
#Intestine Small: Ileum: Polyp Adenomatous								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
fintestine Small: Jejunum: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Carcinoma								
		4/50 (8%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	6/300 (2%)	Mean 2%	SD 3.35%	Total	0/300 (0%)	Mean 0%	SD 0%
fIntestine Small: Jejunum: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma								
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Adenoma

**Overall Incidence** 

Carcinoma

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

Leiomyosarcoma

Hemangiosarcoma

Length of Study: CHRONIC

#Intestine Small: Site Unspecified:

#Intestine Small: Site Unspecified:

#Intestine Small: Site Unspecified:

#Intestine Small: Site Unspecified:

#Intestine Small: Site Unspecified: Carcinoma or Adenoma

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

0/50

0/50

SD 0%

0/50

0/50

SD 0%

(0%)

(0%)

(0%)

(0%)

Total

Total

**Route: INHALATION** Vehicle: AIR Male **Female** (0%)2/50 (4%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(2%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)1/50 (2%)2/300 (0.67%) Mean 1.33% SD 1.63% Total Mean 0.67% SD 1.03% (8%) (0%)0/50 (0%)2/50 (4%)0/50 1/50 (2%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)Mean 2% SD 3.35% Total 2/300 (0.67%) Mean 0.67% SD 1.03% (8%)2/50 (4%)2/50 (4%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (2%)0/50 (0%)1/50 (2%)1/50 (2%)(0%)2/50 (4%)Mean 3.33% SD 2.73% 4/300 (1.33%) Mean 1.33% SD 1.63% Total

0/50

0/50

0/50

0/50

1/300 (0.33%)

0/300 (0%)

(0%)

(0%)

(0%)

(0%)

0/50

0/50

0/50

1/50

(0%)

(0%)

(0%)

(2%)

Mean 0%

Mean 0.33%

0/50

0/50

0/50

0/50

SD 0%

SD 0.82%

(0%)

(0%)

(0%)

(0%)

Page: 148

Report Date: 06/05/2013

*.	Danaminatar ia	 animanla mith	ticourse eversing	d microsconically

Total

Total

Total

Total

Total

0/50

1/50

4/300 (1.33%)

4/50

0/50

6/300 (2%)

4/50

1/50

10/300 (3.33%)

0/50

0/50

0/300 (0%)

0/50

0/50

0/300 (0%)

(0%)

(0%)

(0%)

(0%)

0/50

0/50

0/50

0/50

Mean 0%

Mean 0%

(0%)

(0%)

(0%)

(0%)

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 149 **Report Date:** 06/05/2013

			Male				Female	
#Intestine Small: Site Unspe Polyp Adenomatous	ecified:							
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
'Islets, Pancreatic: Adenoma								
		0/48 (0%)	0/49 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	2/49 (4%)	2/50 (4%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	8/296 (2.7%)	Mean 2.68%	SD 2.08%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
*Islets, Pancreatic: Carcinoma								
		0/48 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/296 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
'Islets, Pancreatic: Carcinoma or Adenoma								
		0/48 (0%)	0/49 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	2/49 (4%)	2/50 (4%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	8/296 (2.7%)	Mean 2.68%	SD 2.08%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
*Kidney: Pelvis and Transiti Carcinoma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 150

			Male				Female	
Kidney: Pelvis and Transitio Carcinoma or Adenoma	onal Epitheliu	ım:						
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Kidney: Renal Tubule: Adenoma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
'Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
'Kidney: Renal Tubule: Hemangioma								
_		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 151

			Male				Female	
Kidney: Renal Tubule: Hemangiosarcoma								
		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/298 (0.34%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Plasma Cell Tumor Malig								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/298 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
'Kidney: Renal Tubule: Sarcoma Overall Incidence	Total	0/49 (0%) 0/50 (0%) 0/298 (0%)	0/50 (0%) 0/49 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%
Liver: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Liver: Hemangiosarcoma								
-		1/50 (2%)	4/50 (8%)	2/50 (4%)		0/50 (0%)	2/50 (4%)	1/50 (2%)
Overall Incidence	Total	0/50 (0%) 10/299 (3.34%)	1/49 (2%) Mean 3.34%	2/50 (4%) SD 2.73%	Total	0/50 (0%) 6/300 (2%)	2/50 (4%) Mean 2%	1/50 (2%) SD 1.79%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 152

Report Date: 06/05/2013

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
Liver: Hepatoblastoma								
		1/50 (2%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	5/299 (1.67%)	Mean 1.67%	SD 1.51%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Liver: Hepatocellular Adenom	a							
		30/50 (60%)	28/50 (56%)	28/50 (56%)		19/50 (38%)	19/50 (38%)	14/50 (28%)
		24/50 (48%)	33/49 (67%)	37/50 (74%)		14/50 (28%)	14/50 (28%)	25/50 (50%)
verall Incidence	Total	180/299 (60.2%)	Mean 60.22%	SD 9.23%	Total	105/300 (35%)	Mean 35%	SD 8.83%
Liver: Hepatocellular Carcinor	na							
		15/50 (30%)	25/50 (50%)	20/50 (40%)		5/50 (10%)	10/50 (20%)	4/50 (8%)
		11/50 (22%)	11/49 (22%)	26/50 (52%)		10/50 (20%)	7/50 (14%)	8/50 (16%)
Overall Incidence	Total	108/299 (36.12%)	Mean 36.07%	SD 13.29%	Total	44/300 (14.67%)	Mean 14.67%	SD 5.01%
Liver: Hepatocellular Carcinor	na or Hepatob	lastoma						
	-	16/50 (32%)	27/50 (54%)	20/50 (40%)		5/50 (10%)	10/50 (20%)	4/50 (8%)
		11/50 (22%)	11/49 (22%)	27/50 (54%)		10/50 (20%)	7/50 (14%)	8/50 (16%)
Overall Incidence	Total	112/299 (37.46%)	Mean 37.41%	SD 14.48%	Total	44/300 (14.67%)	Mean 14.67%	SD 5.01%
Liver: Hepatocellular Carcinor	na or Hepatoc	ellular Adenoma						
-	•	38/50 (76%)	38/50 (76%)	40/50 (80%)		24/50 (48%)	25/50 (50%)	16/50 (32%)
		32/50 (64%)	37/49 (76%)	44/50 (88%)		20/50 (40%)	20/50 (40%)	28/50 (56%)
Overall Incidence	Total	229/299 (76.59%)	Mean 76.59%	SD 7.77%	Total	133/300 (44.33%)	Mean 44.33%	SD 8.62%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Page: 153

Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
*Liver:								
Hepatocellular Carcinoma, I	Hepatocei			10/20 (000)			( ()	10/00 (000)
		38/50 (76%)	39/50 (78%)	40/50 (80%)		24/50 (48%)	25/50 (50%)	16/50 (32%)
		32/50 (64%)	37/49 (76%)	45/50 (90%)		20/50 (40%)	20/50 (40%)	28/50 (56%)
Overall Incidence	Total	231/299 (77.26%)	Mean 77.25%	SD 8.38%	Total	133/300 (44.33%)	Mean 44.33%	SD 8.62%
*Liver: Hepatocholangiocarcinoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/300 (0%)	Mean 0%	SD 0%
*Liver: Hepatocholangioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
*Liver: Ito Cell Tumor Benign								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
*Liver: Mast Cell Tumor Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

**Page:** 154

Report Date: 06/05/2013

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
Liver: Plasma Cell Tumor Mal	lignant							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Liver: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
'Lung: Alveolar/Bronchiolar A		6/50 (12%) 5/50 (10%)	7/50 (14%) 10/50 (20%)	4/50 (8%) 7/50 (14%)		1/50 (2%) 1/50 (2%)	3/49 (6%) 6/50 (12%)	2/50 (4%) 3/50 (6%)
Overall Incidence	Total	39/300 (13%)	Mean 13%	SD 4.15%	Total	16/299 (5.35%)	Mean 5.35%	SD 3.73%
Lung: Alveolar/Bronchiolar C	arcinoma							
		8/50 (16%)	11/50 (22%)	12/50 (24%)		0/50 (0%)	5/49 (10%)	3/50 (6%)
		8/50 (16%)	11/50 (22%)	9/50 (18%)		4/50 (8%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	59/300 (19.67%)	Mean 19.67%	SD 3.44%	Total	13/299 (4.35%)	Mean 4.37%	SD 4.33%
Lung: Alveolar/Bronchiolar C	arcinoma or Al	veolar/Bronchiolar Adeno	ma					
		13/50 (26%)	16/50 (32%)	15/50 (30%)		1/50 (2%)	8/49 (16%)	5/50 (10%)
		13/50 (26%)	20/50 (40%)	13/50 (26%)		4/50 (8%)	6/50 (12%)	4/50 (8%)
Overall Incidence	Total	90/300 (30%)	Mean 30%	SD 5.51%	Total	28/299 (9.36%)	Mean 9.39%	SD 4.77%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 155

			Male				Female	
Lung: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%
Lung: Plasma Cell Tumor Malig	nant							
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
#Lymph Node: Plasma Cell Tumor Malig	nant	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Lymph Node, Bronchial: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Lymph Node, Mandibular: Hemangiosarcoma								
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 156

			Male				Female	
Lymph Node, Mandibular: Mast Cell Tumor Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Lymph Node, Mandibular: Plasma Cell Tumor Malignan	ıt							
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Lymph Node, Mediastinal: Mast Cell Tumor Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Lymph Node, Mesenteric: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Lymph Node, Mesenteric: Plasma Cell Tumor Malignan								
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Mammary Gland: Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/300 (0%) **Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total Mean 0% SD 0% #Mammary Gland: Carcinoma (0%)(4%)0/50 0/50 (0%)0/50 (0%)2/50 1/50 (2%)4/50 (8%)0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)1/50 (2%)1/50 (2%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 11/300 (3.67%) Mean 3.67% SD 2.34% .......... **#Mammary Gland:** Carcinoma or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)1/50 (2%)4/50 (8%)0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)1/50 (2%)1/50 (2%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% 11/300 (3.67%) Mean 3.67% SD 2.34% Total **#Mammary Gland:** Fibroadenoma 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 1/300 (0.33%) Mean 0.33% SD 0.82% #Mammary Gland: Fibroma, Fibroadenoma or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 0%

Total

1/300 (0.33%)

Total

0/300 (0%)

Mean 0%

**Overall Incidence** 

Page: 157

Mean 0.33%

SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Page: 158

Report Date: 06/05/2013

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
Mammary Gland:	. 0	. • .						
Fibroma, Fibroadenom	a, Carcinoma, o		0/50 (00/)	0/50 (00/)		0/50 (40/)	4/50 (00/)	F/F0 /400/)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		2/50 (4%) 2/50 (4%)	1/50 (2%)	5/50 (10%)
N 11 In 1 . 1	T-1-1	` '	` '	0/50 (0%)	T-1-1	, ,	1/50 (2%)	1/50 (2%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	12/300 (4%)	Mean 4%	SD 3.1%
Mesentery: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
Mesentery: Hemangiosarcoma  Overall Incidence	Total	0/50 (0%) 0/50 (0%) 1/300 (0.33%)	0/50 (0%) 0/50 (0%) Mean 0.33%	1/50 (2%) 0/50 (0%) SD 0.82%	Total	1/50 (2%) 0/50 (0%) 4/300 (1.33%)	0/50 (0%) 1/50 (2%) Mean 1.33%	2/50 (4%) 0/50 (0%) SD 1.63%
Mesentery: Lipoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Mesentery: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Nose: Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) (0%)0/50 (0%)0/49 (0%)0/50 0/50 (0%)0/50 0/50 (0%)0/300 (0%) **Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total Mean 0% SD 0% \*Nose: Hemangiosarcoma (0%)(0%)0/50 0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% **#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):** Papilloma Squamous or Papilloma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% 0/300 (0%) Mean 0% SD 0% Total **#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma** 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0%

Page: 159

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 160

			Male				Female	
Oral Mucosa: Squamous Cell Carcinom	na							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Ovary: Choriocarcinoma								
						0/50 (0%) 0/50 (0%)	0/48 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)
Overall Incidence					Total	0/297 (0%)	Mean 0%	SD 0%
Ovary: Cystadenocarcinoma								
						0/50 (0%)	0/48 (0%)	0/49 (0%)
Overall Incidence					Total	0/50 (0%) 0/297 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Ovary: Cystadenoma								
•						3/50 (6%)	1/48 (2%)	3/49 (6%)
Overall Incidence					Total	2/50 (4%) 12/297 (4.04%)	2/50 (4%) Mean 4.03%	1/50 (2%) SD 1.8%
Ovary: Granulosa Cell Tumor Be	enign							
	J					0/50 (0%)	0/48 (0%)	0/49 (0%)
Overall Incidence					Total	1/50 (2%) 1/297 (0.34%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Page: 161

Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

	Male			Female	
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS					
Grandiosa cen ramor. Benign, manghant, 1100			0/50 (0%)	0/48 (0%)	0/49 (0%)
			1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	1/297 (0.34%)	Mean 0.33%	SD 0.82%
Ovary: Hemangioma					
-			0/50 (0%)	0/48 (0%)	0/49 (0%)
			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/297 (0%)	Mean 0%	SD 0%
Ovary: Hemangiosarcoma					
-			0/50 (0%)	0/48 (0%)	1/49 (2%)
			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	1/297 (0.34%)	Mean 0.34%	SD 0.83%
'Ovary: Luteoma					
			1/50 (2%)	0/48 (0%)	0/49 (0%)
			1/50 (2%)	1/50 (2%)	1/50 (2%)
Overall Incidence		Total	4/297 (1.35%)	Mean 1.33%	SD 1.03%
Ovary: Plasma Cell Tumor Malignant					
-			0/50 (0%)	0/48 (0%)	0/49 (0%)
			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/297 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 162

Report Date: 06/05/2013

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Ovary: Sarcoma 0/50 (0%)0/48 (0%)0/49 (0%)0/50 0/50 (0%)(0%)0/50 (0%)**Overall Incidence** Total 0/297 (0%) Mean 0% SD 0% \*Ovary: Teratoma Benign 0/50 (0%)0/48 (0%)0/49 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/297 (0.34%) Mean 0.33% SD 0.82% ..... \*Ovary: **Teratoma Malignant** 0/50 0/48 (0%)0/49 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/297 (0.34%) Mean 0.33% SD 0.82% \*Ovary: **Tubulostromal Adenoma** 0/50 (0%)0/48 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/297 (0%) Mean 0% SD 0% \*Ovary: **Yolk Sac Carcinoma** 0/50 (0%)1/48 0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/297 (0.34%) Mean 0.35% SD 0.85% .....

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

**Page:** 163

Report Date: 06/05/2013

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
Pancreas: Carcinoma								
		1/48 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/297 (0.34%)	Mean 0.35%	SD 0.85%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Pancreas: Carcinoma or Adenoma								
		1/48 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/297 (0.34%)	Mean 0.35%	SD 0.85%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Pituitary Gland: Pars Dista Adenoma Overall Incidence	i <b>lis or Unspec</b> Total	ified Site:  1/46 (2%) 0/50 (0%) 1/292 (0.34%)	0/47 (0%) 0/50 (0%) Mean 0.36%	0/50 (0%) 0/49 (0%) SD 0.89%	Total	5/46 (11%) 5/50 (10%) 37/292 (12.67%)	3/47 (6%) 6/49 (12%) Mean 12.58%	10/50 (20%) 8/50 (16%) SD 4.79%
Pituitary Gland: Pars Dista Carcinoma	llis or Unspec	ified Site:						
		0/46 (0%)	0/47 (0%)	0/50 (0%)		1/46 (2%)	0/47 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/292 (0%)	Mean 0%	SD 0%	Total	1/292 (0.34%)	Mean 0.36%	SD 0.89%
Pituitary Gland: Pars Dista Carcinoma or Adenoma								
		1/46 (2%)	0/47 (0%)	0/50 (0%)		6/46 (13%)	3/47 (6%)	10/50 (20%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		5/50 (10%)	6/49 (12%)	8/50 (16%)
Overall Incidence	Total	1/292 (0.34%)	Mean 0.36%	SD 0.89%	Total	38/292 (13.01%)	Mean 12.95%	SD 4.72%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

## **Toxicology Data Management System**

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 164

			Male				Female	
Pituitary Gland: Pars Interm Adenoma	edia:							
		0/46 (0%)	0/47 (0%)	0/50 (0%)		0/46 (0%)	0/47 (0%)	2/50 (4%)
Overall Incidence	Total	0/50 (0%) 1/292 (0.34%)	0/50 (0%) Mean 0.34%	1/49 (2%) SD 0.83%	Total	0/50 (0%) 3/292 (1.03%)	1/49 (2%) Mean 1.01%	0/50 (0%) SD 1.68%
*Pituitary Gland: Pars Interm Carcinoma or Adenoma								
		0/46 (0%)	0/47 (0%)	0/50 (0%)		0/46 (0%)	0/47 (0%)	2/50 (4%)
		0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%)	1/49 (2%)	0/50 (0%)
Overall Incidence	Total	1/292 (0.34%)		SD 0.83%	Total	3/292 (1.03%)	Mean 1.01%	SD 1.68%
*Salivary Glands: Adenoma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenoma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
*Salivary Glands: Hemangiosarcoma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 165

			Male				Female	
*Salivary Glands: Mast Cell Tumor Malignan	it							
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
*Salivary Glands: Myxoma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
#Seminal Vesicle: Adenoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%				
#Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Skeletal Muscle: Rhabdomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>.</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE Strain: B6C3F1 Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Male **Female #Skeletal Muscle:** Rhabdomyosarcoma or Rhabdomyoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/300 (0%) **Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total Mean 0% SD 0% **#Skeletal Muscle:** Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 1/300 (0.33%) Mean 0.33% SD 0.82% #Skin: **Basal Cell Carcinoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% 0/300 (0%) Mean 0% SD 0% Total #Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% #Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0%

Page: 166

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE Strain: B6C3F1 **Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)SD 0.82% **Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% Total 1/300 (0.33%) Mean 0.33% #Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma 0/50 (0%)0/50 (0%)1/50 (2%)8/50 (16%)2/50 (4%)4/50 (8%)(0%) 0/50 2/50 (4%)1/50 2/50 (2%)0/50 (0%)1/50 (2%)(4%)4/300 (1.33%) Mean 1.33% SD 1.63% SD 5.72% **Overall Incidence** Total Total 17/300 (5.67%) Mean 5.67% #Skin: **Fibrosarcoma** 0/50 0/50 0/50 0/50 0/50 (0%)(0%)(0%)0/50 (0%)(0%)(0%)(0%) 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total 1/300 (0.33%) Mean 0.33% SD 0.82% #Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma 0/50 (0%)0/50 (0%)1/50 (2%)8/50 2/50 4/50 (8%)(16%)(4%)(0%)0/50 2/50 (4%)1/50 (2%)0/50 (0%)1/50 (2%)2/50 (4%)**Overall Incidence** Total 4/300 (1.33%) Mean 1.33% SD 1.63% Total 17/300 (5.67%) Mean 5.67% SD 5.72% #Skin: **Fibrous Histiocytoma** 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 2/300 (0.67%) Mean 0.67% SD 1.03% Total 1/300 (0.33%) Mean 0.33% SD 0.82%

Page: 167

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 168

			Male				Female	
#Skin: Granular Cell Tumor Be	nign							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
O	Taral	0/50 (0%)	1/50 (2%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	2/50 (4%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/300 (1%)	Mean 1%	SD 1.67%	Total	3/300 (1%)	Mean 1%	SD 1.67%
#Skin: Keratoacanthoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Lipoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	<b>.</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>+</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page**: 169

			Male				Female	
#Skin: Liposarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Mast Cell Tumor Benign								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Mast Cell Tumor Malignant Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%
≄Skin: Melanoma Benign		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Melanoma Malignant		0/50 (0%/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/.)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION

**Page:** 170

Report Date: 06/05/2013

Strain: B6C3F1 Length of Study: CHRONIC Vehicle: AIR

			Male				Female	
Skin: Neural Crest Tumor								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/50 (0%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%	Total	0/50 (0%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%
		1/300 (0.33%)		3D 0.02%	10tai	1/300 (0.33%)		3D 0.02%
Skin: Neurofibroma or Schw	vannoma benign							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Skin: Neurofibrosarcoma or Overall Incidence	Schwannoma (m	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%
Skin:								
Neurotibrosarcoma, N	eurofibroma, or	Schwannoma (benign, m 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Skin: Osteosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

13 To

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 171

			Male				Female	
#Skin: Sarcoma								
		0/50 (0%)	0/50 (0%)	1/50 (2%)		7/50 (14%)	2/50 (4%)	4/50 (8%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	Total	15/300 (5%)	Mean 5%	SD 5.18%
#Skin: Schwannoma Benign								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma, or Carcinoma						0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
		` '				` '		
#Skin: Squamous Cell Papilloma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 172

Report Date: 06/05/2013

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
#Skin:								
Squamous Cell Papilloma	or Papilloma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Skin:								
Squamous Cell Papilloma	i, Papilloma, S	Squamous Cell Carcinor	na or Keratoacanthoma					
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Squamous Cell Papilloma Overall Incidence	Total	0/50 (0%) 0/50 (0%) 1/300 (0.33%)	0/50 (0%) 0/50 (0%) Mean 0.33%	0/50 (0%) 1/50 (2%) SD 0.82%	Total	0/50 (0%) 1/50 (2%) 1/300 (0.33%)	0/50 (0%) 0/50 (0%) Mean 0.33%	0/50 (0%) 0/50 (0%) SD 0.82%
#Skin: Sebaceous Gland:								
Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
		0/300 (0%)	IVIEAN U%		ı Olai			
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 173 Report Date: 06/05/2013

			Male				Female	
Spinal Cord: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Spleen: Hemangioma								
		0/48 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
'Spleen: Hemangiosarcoma								
		2/48 (4%)	3/50 (6%)	3/50 (6%)		1/50 (2%)	2/49 (4%)	2/50 (4%)
		0/50 (0%)	1/49 (2%)	2/50 (4%)		1/50 (2%)	1/50 (2%)	3/50 (6%)
Overall Incidence	Total	11/297 (3.7%)	Mean 3.7%	SD 2.34%	Total	10/299 (3.34%)	Mean 3.35%	SD 1.64%
Spleen: Mast Cell Tumor Malignant								
		0/48 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/49 (2%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	1/299 (0.33%)	Mean 0.34%	SD 0.83%
Spleen: Plasma Cell Tumor Maligna								
		0/48 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 174 Report Date: 06/05/2013

			Male				Female	
#Stomach, Forestomach: Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.63%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Stomach, Forestomach: Squamous Cell Carcinoma	or Papillom	na Squamous						
1		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	3/300 (1%)	Mean 1%	SD 1.67%	Total	3/300 (1%)	Mean 1%	SD 1.1%
#Stomach, Forestomach: Squamous Cell Papilloma		0/50 (0%)		0/50 (0%)			1/50 (29/)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)		0/50 (0%) 0/50 (0%)	1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
#Stomach, Glandular: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Stomach, Glandular: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 175

			Male				Female	
#Stomach, Glandular: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/50 (2%)	0/50 (0%) Mean 0.33%	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	1/50 (2%)
	Total	1/300 (0.33%)		SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
*Testes: Adenoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)				
Overell Incidence	Tatal	0/50 (0%)	0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%				
*Testes: Hemangioma								
_		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%				
*Thymus: Neoplasm NOS								
·		0/38 (0%)	0/42 (0%)	0/38 (0%)		0/49 (0%)	1/46 (2%)	0/47 (0%)
		0/41 (0%)	0/47 (0%)	0/39 (0%)		0/44 (0%)	0/48 (0%)	0/47 (0%)
Overall Incidence	Total	0/245 (0%)	Mean 0%	SD 0%	Total	1/281 (0.36%)	Mean 0.36%	SD 0.89%
*Thymus: Thymoma Benign								
		0/38 (0%)	0/42 (0%)	0/38 (0%)		0/49 (0%)	0/46 (0%)	0/47 (0%)
		0/41 (0%)	0/47 (0%)	0/39 (0%)		0/44 (0%)	0/48 (0%)	0/47 (0%)
Overall Incidence	Total	0/245 (0%)	Mean 0%	SD 0%	Total	0/281 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

**Page:** 176

			Male				Female	
Thymus: Thymoma Malignant								
		0/38 (0%)	0/42 (0%)	0/38 (0%)		0/49 (0%)	0/46 (0%)	0/47 (0%)
		0/41 (0%)	0/47 (0%)	0/39 (0%)		0/44 (0%)	0/48 (0%)	0/47 (0%)
Overall Incidence	Total	0/245 (0%)	Mean 0%	SD 0%	Total	0/281 (0%)	Mean 0%	SD 0%
'Thymus: Thymoma: Benign, Maligna	ant, NOS							
		0/38 (0%)	0/42 (0%)	0/38 (0%)		0/49 (0%)	0/46 (0%)	0/47 (0%)
		0/41 (0%)	0/47 (0%)	0/39 (0%)		0/44 (0%)	0/48 (0%)	0/47 (0%)
Overall Incidence	Total	0/245 (0%)	Mean 0%	SD 0%	Total	0/281 (0%)	Mean 0%	SD 0%
Thyroid Gland: C-Cell: Carcinoma								
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Thyroid Gland: Follicular Ce Adenoma	ell:							
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
*Thyroid Gland: Follicular Cel Carcinoma	II:							
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
*Thyroid Gland: Follicular Cel Carcinoma or Adenoma	II:							
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%
#Tissue NOS: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Tissue NOS: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Tissue NOS: Plasma Cell Tumor Maligna								
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

Page: 177

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 178
Report Date: 06/05/2013

			Male				Female	
Tissue NOS: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Tongue: Fibroma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcine Overall Incidence	oma or Papilloma Total	a Squamous 0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%
FTongue: Squamous Cell Papillo	oma	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Tooth: Odontoma		-1						- 10-
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/300 (1%)	Mean 1%	SD 1.67%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Page: 179

Report Date: 06/05/2013

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Male **Female** #Urethra: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/300 (0%) **Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% Total Mean 0% SD 0% \*Urinary Bladder: Hemangiosarcoma (2%)0/47(0%)0/48 (0%)0/50 (0%)1/50 0/49 (0%)0/50 (0%)1/50 (2%)0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/49 (0%)**Overall Incidence** Total 1/294 (0.34%) Mean 0.33% SD 0.82% Total 1/297 (0.34%) Mean 0.33% SD 0.82% ..... \*Urinary Bladder: **Plasma Cell Tumor Malignant** 0/47 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/49 (0%)**Overall Incidence** Total 0/294 (0%) Mean 0% SD 0% Total 0/297 (0%) Mean 0% SD 0% #Uterus: Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% **#Uterus:** Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 180

Report Date: 06/05/2013

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

	Male			Female	
Uterus:					
Hemangiosarcoma			0/50 (00/)	0/50 (00/)	0/50 (00/)
			0/50 (0%) 1/50 (2%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 1/50 (2%)
Overall Incidence		Total	3/300 (1%)	Mean 1%	SD 1.1%
			` ,		
Uterus: Leiomyoma					
			0/50 (0%)	0/50 (0%)	0/50 (0%)
			1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Uterus: Leiomyosarcoma			0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence		Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Uterus: Polyp Stromal			•••••		
•			0/50 (0%)	2/50 (4%)	1/50 (2%)
			0/50 (0%)	1/50 (2%)	2/50 (4%)
verall Incidence		Total	6/300 (2%)	Mean 2%	SD 1.79%
Uterus: Sarcoma					
			0/50 (0%)	0/50 (0%)	0/50 (0%)
			0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence		Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 181

					Male						F	emale		
#Uterus: Sarcoma Stromal														
									0/50 (0° 0/50 (0°		0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)
Overall Incidence								Total	0/300 (0%)	,	Mea	า 0%	SD	0%
#Uterus: Sarcoma Stromal or Polyp S														
									0/50 (09	,	2/50	(4%)	1/50	(2%)
Overall Incidence								Total	0/50 (0° 6/300 (2%)	%)	1/50 Meai	(2%) n 2%	2/50 SD 1	(4%) .79%
											•••••			
#Vagina: Liposarcoma														
Liposarcoma									0/50 (09	%)	0/50	(0%)	0/50	(0%)
									0/50 (09	,	0/50	(0%)	0/50	(0%)
Overall Incidence								Total	0/300 (0%)		Mea	า 0%	SD	0%
#Zymbal's Gland: Carcinoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50 (09		0/50	(0%)	0/50	(0%)
			(0%)	0/50	(0%)	0/50	(0%)		0/50 (09	%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/300 (0%)		Mean	0%	SD 0%		Total	0/300 (0%)		Mea	า 0%	SD	0%
#Zymbal's Gland: Carcinoma or Adenoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50 (09	,	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/50 0/300 (0%)	(0%)	0/50 Mean	(0%)	0/50 SD 0%	(0%)	Total	0/50 (0° 0/300 (0%)	%)	0/50 Meai	(0%)	0/50 SD	(0%)
Overall incluence	i Ulai	0/300 (0%)		iviean	U /0	3D 0%		TULAI	0/300 (0%)		ivieal	I U70	30	U /0

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Page: 182

Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

# **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Columbus Laboratory Battelle Columbus Laboratory	052000904 059601406	11/09/04 09/26/06	730 730	50(1) 50(1)	24(645) 25(660)	57.1 55.9	beta-Picoline Water disinfection byproducts (Bromodichloroacetic acid)
					Female		
Battelle Columbus Laboratory Battelle Columbus Laboratory	052000904 059601406	11/08/04 09/25/06	729 729	50(5) 50(5)	38(702) 30(680)	67.4 63.5	beta-Picoline Water disinfection byproducts (Bromodichloroacetic acid)

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Page: 183

Report Date: 06/05/2013

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Male **Female** #All Organs: **Benign Tumors** 36/50 (72%)43/50 (86%)40/50 (80%)36/50 (72%)**Overall Incidence** Total 79/100 (79%) Mean 79% SD 9.9% Total 76/100 (76%) Mean 76% SD 5.66% #All Organs: **Malignant Tumors** 36/50 (72%)30/50 (60%)29/50 (58%)31/50 (62%)**Overall Incidence** Total 66/100 (66%) Mean 66% SD 8.49% Total 60/100 (60%) Mean 60% SD 2.83% #All Organs: **Malignant and Benign Tumors** 48/50 (96%)48/50 (96%)43/50 (86%)45/50 (90%) Overall Incidence Total 96/100 (96%) Mean 96% SD 0% Total 88/100 (88%) Mean 88% SD 2.83% ..... #All Organs: Hemangioma 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%) Mean 0% SD 0% ....... **#All Organs:** Hemangiosarcoma 6/50 (12%)5/50 (10%)3/50 (6%)6/50 (12%) **Overall Incidence** Total 11/100 (11%) Mean 11% SD 1.41% Total 9/100 (9%) Mean 9% SD 4.24% **#All Organs:** Hemangiosarcoma or Hemangioma 7/50 (14%)5/50 (10%)3/50 (6%)6/50 (12%) **Overall Incidence** 12/100 (12%) Mean 12% SD 2.83% 9/100 (9%) Mean 9% SD 4.24% Total Total

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 184

			Male				Female	Female		
#All Organs: Histiocytic Sarcoma										
		0/50 (0%)	1/50 (2%)			1/50 (2%)	2/50 (4%)			
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	3/100 (3%)	Mean 3%	SD 1.41%		
#All Organs: Malignant Lymphoma: Hi	stiocytic, Lym	phocytic, Mixed, NOS, or	Undifferentiated Cel	I Туре						
		0/50 (0%)	0/50 (0%)			14/50 (28%)	6/50 (12%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	20/100 (20%)	Mean 20%	SD 11.31%		
#All Organs: Mesothelioma: Benign										
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%		
#All Organs: Mesothelioma: Benign, N										
		1/50 (2%)	1/50 (2%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#All Organs: Mesothelioma: Malignant										
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%		
#All Organs: Osteoma										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 185

			Male				Female	
#All Organs: Osteosarcoma		0/50 (00/)	0/50 /00/			0/50 (40/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%
#All Organs: Osteosarcoma or Osteoma	1	0/50 (0%)	0/50 (0%)			2/50 (4%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 1.41%
*Adrenal Cortex: Adenoma		2/49 (4%)	2/50 (4%)			0/49 (0%)	0/49 (0%)	
Overall Incidence	Total	4/99 (4.04%)	Mean 4.04%	SD 0.06%	Total	0/98 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Plasma Cell Tumor Maligna	ant	0/49 (0%)	0/50 (0%)			0/49 (0%)	0/49 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Benig	n	0/49 (0%)	0/50 (0%)			1/49 (2%)	0/50 (0%)	
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%
*Adrenal Medulla: Pheochromocytoma Maligr	nant							•••••
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 186 Report Date: 06/05/2013

			Male				Female				
*Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS  0/49 (0%) 0/50 (0%)  1/49 (2%) 0/50 (0%)											
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%			
#Blood Vessel: Hemangioma											
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
*Bone Marrow: Hemangioma		0/50 /00/	0/50 (00)			0/40 (0%)	0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%			
*Bone Marrow: Hemangiosarcoma		2/50 (4%)	0/50 (0%)			1/49 (2%)	0/50 (0%)				
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%			
*Bone Marrow: Mast Cell Tumor Malignal	nt										
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%			
*Bone Marrow: Plasma Cell Tumor Malig	nant	0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	0/50 (0%) Mean 0%	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 187

			Male			Female			
*Bone Marrow: Sarcoma		0/50 (00/)	0/50 (00/)			0/40 (00/)	0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Bone: Fibroma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Bone: Hemangiosarcoma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Bone: Osteoma									
Overall Incidence	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%	
#Bone: Osteosarcoma		•••••			•••••				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%	
#Bone: Osteosarcoma or Osteoma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 188

			Male				Female	
#Bone: Sarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	25.00
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Granular Cell Tumor Ber	nign	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Brain: Meningioma Benign		0/20 (00)	(201)			2/22 (221)	(00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
*Brain: Meningioma Malignant		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/99 (0%)	Mean 0%	SD 0%
*Brain: Meningioma: Benign, Ma	alignant, NOS	0/50 (0%)	1/50 (2%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/99 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma Mali	gnant							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 189

			Male				Female					
*Brain: Oligodendroglioma, Glioma, or Astrocytoma												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%				
*Brain: Schwannoma Malignant												
		0/50 (0%)	0/50 (0%)	00.00/		0/50 (0%)	0/49 (0%)	00.00				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%				
*Clitoral/Preputial Gland: Hemangioma												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/47 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/97 (0%)	Mean 0%	SD 0%				
*Clitoral/Preputial Gland: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/47 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/97 (0%)	Mean 0%	SD 0%				
#Coagulating Gland: Granular Cell Tumor												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Coagulating Gland: Sarcoma		0/50 (00)	0/50 /00/			0/50 (00/)	0/50 (00)					
Occupation of days a	T-1-1	0/50 (0%)	0/50 (0%)	00.00/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 190

			Male				Female			
#Esophagus: Squamous Cell Carcinoma	1									
•		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Eye: Melanoma Malignant										
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Harderian Gland: Adenoma										
		5/50 (10%)	6/50 (12%)			2/50 (4%)	5/50 (10%)			
Overall Incidence	Total	11/100 (11%)	Mean 11%	SD 1.41%	Total	7/100 (7%)	Mean 7%	SD 4.24%		
#Harderian Gland: Carcinoma										
	<b>-</b>	2/50 (4%)	0/50 (0%)	00.000/	<b>-</b>	2/50 (4%)	0/50 (0%)	00.000/		
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	2/100 (2%)	Mean 2%	SD 2.83%		
#Harderian Gland: Carcinoma or Adenoma										
		7/50 (14%)	6/50 (12%)			4/50 (8%)	5/50 (10%)			
Overall Incidence	Total	13/100 (13%)	Mean 13%	SD 1.41%	Total	9/100 (9%)	Mean 9%	SD 1.41%		
*Heart: Hemangiosarcoma										
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 191

Report Date: 06/05/2013

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Intestine Large: Cecum: Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% #Intestine Large: Cecum: Carcinoma 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%) Mean 0% SD 0% #Intestine Large: Cecum: Carcinoma or Adenoma 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%) Mean 0% SD 0% ..... #Intestine Large: Cecum: Leiomyoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% ..... #Intestine Large: Cecum: Leiomyosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% #Intestine Large: Colon/Rectum: Leiomyosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% 0/100 (0%) Mean 0% SD 0% Total

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 192

			Male				Female	
#Intestine Small: Duodenum: Adenoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Carcinoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Polyp Adenomatous						0(50 (00())	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
						` '		
#Intestine Small: Ileum: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Carcinoma		0/50 (00)	0/50 (00/)			2/52 (221)	0/50 (00/)	
Overell Institutes	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 193

			Male				Female	
#Intestine Small: Ileum: Polyp Adenomatous								
•		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Carcinoma								
		2/50 (4%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
		0/100 (0%)				` '		ט ע%
#Intestine Small: Jejunum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec Adenoma	ified:							
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 194

			Male				Female	
#Intestine Small: Site Unsp Carcinoma	ecified:							
Overall Incidence	Total	2/50 (4%) 4/100 (4%)	2/50 (4%) Mean 4%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Site Unsp Carcinoma or Adenoma	ecified:		•••••					
Overall Incidence	Total	2/50 (4%) 5/100 (5%)	3/50 (6%) Mean 5%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Site Unsp Hemangiosarcoma	ecified:							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Site Unsp Leiomyosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Site Unsp Polyp Adenomatous			•••••					•••••
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma			(0.5)			(00)		
Overall Incidence	Total	1/49 (2%) 1/99 (1.01%)	0/50 (0%) Mean 1.02%	SD 1.44%	Total	0/48 (0%) 0/97 (0%)	0/49 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 195

Report Date: 06/05/2013

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Islets, Pancreatic: Carcinoma 0/49 (0%)0/50 (0%)0/48 (0%)0/49 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% Total 0/97 (0%) Mean 0% SD 0% \*Islets, Pancreatic: Carcinoma or Adenoma 1/49 (2%)0/50 (0%)0/48 (0%)0/49 (0%)**Overall Incidence** Total 1/99 (1.01%) Mean 1.02% SD 1.44% Total 0/97 (0%) Mean 0% SD 0% \*Kidney: Pelvis and Transitional Epithelium: Carcinoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/99 (0%) Mean 0% SD 0% \*Kidney: Pelvis and Transitional Epithelium: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total Mean 0% SD 0% 0/99 (0%) \*Kidney: Renal Tubule: Adenoma 0/50 (0%)2/50 (4%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 2/100 (2%) Mean 2% SD 2.83% Total 0/99 (0%) Mean 0% SD 0% \*Kidney: Renal Tubule: Carcinoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% Mean 0% SD 0% 0/100 (0%) Total 0/99 (0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 196

			Male		0/49 (0%) 0/50 (0%) 0% Total 0/99 (0%) Mean 0%  0/49 (0%) 0/50 (0%) 0% Total 0/99 (0%) Mean 0%  0/49 (0%) 0/50 (0%) 0% Total 0/99 (0%) Mean 0%			
*Kidney: Renal Tubule: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%	Total	` ,	()	SD 0%
*Kidney: Renal Tubule: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` ,	` '	SD 0%
*Kidney: Renal Tubule: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` ,	` '	SD 0%
*Kidney: Renal Tubule: Plasma Cell Tumor Malign			0/50 (0%)			0/40 /00/	0/50 (09/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	Mean 0%	SD 0%		` ,	` ,	SD 0%
*Kidney: Renal Tubule: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` '	` ,	SD 0%
*Liver: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/98 (0%)	0/49 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 197

			Male		1/49 (2%) 0/49 (0%) Total 1/98 (1.02%) Mean 1.02% SD 1  38/49 (78%) 33/49 (67%) Total 71/98 (72.45%) Mean 72.45% SD 7  11/49 (22%) 9/49 (18%) Total 20/98 (20.41%) Mean 20.41% SD 2			Female			
*Liver: Hemangiosarcoma											
		5/50 (10%)	1/50 (2%)			2/49 (4%)	2/49 (4%)				
Overall Incidence	Total	6/100 (6%)	Mean 6%	SD 5.66%	Total	4/98 (4.08%)	Mean 4.08%	SD 0%			
*Liver: Hepatoblastoma											
		6/50 (12%)	4/50 (8%)			` ,	0/49 (0%)				
Overall Incidence	Total	10/100 (10%)	Mean 10%	SD 2.83%	Total	1/98 (1.02%)	Mean 1.02%	SD 1.44%			
*Liver: Hepatocellular Adenoma											
		33/50 (66%)	39/50 (78%)	00 0 1001		` ,	, ,	05			
Overall Incidence	Total	72/100 (72%)	Mean 72%	SD 8.49%	l otal	71/98 (72.45%)	Mean 72.45%	SD 7.22%			
*Liver: Hepatocellular Carcinoma											
		26/50 (52%)	12/50 (24%)			` ,	` '				
Overall Incidence	Total	38/100 (38%)	Mean 38%	SD 19.8%		, ,		SD 2.89%			
*Liver: Hepatocellular Carcinoma o											
-	-	26/50 (52%)	15/50 (30%)			12/49 (24%)	9/49 (18%)				
Overall Incidence	Total	41/100 (41%)	Mean 41%	SD 15.56%	Total	21/98 (21.43%)	Mean 21.43%	SD 4.33%			
*Liver: Hepatocellular Carcinoma o	or Hepatoce		40/50 (0.45)			40/40 (000/)	00/40 (700/)				
Occasillation of the second	T-1-1	45/50 (90%)	42/50 (84%)	OD 4.040/	T-1-1	40/49 (82%)	36/49 (73%)	00 5 770/			
Overall Incidence	Total	87/100 (87%)	Mean 87%	SD 4.24%	Total	76/98 (77.55%)	Mean 77.55%	SD 5.77%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page**: 198

			Male				Female			
*Liver: Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma  45/50 (90%) 42/50 (84%) 40/49 (82%) 36/49 (73%)										
Overall Incidence	Total	45/50 (90%) 87/100 (87%)	42/50 (84%) Mean 87%	SD 4.24%	Total	76/98 (77.55%)	Mean 77.55%	SD 5.77%		
*Liver: Hepatocholangiocarcinor	na	0(50 (40))	0/50 (00/)			0/40 (00/)	0/40 (00/)			
Overall Incidence	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%	Total	0/49 (0%) 0/98 (0%)	0/49 (0%) Mean 0%	SD 0%		
*Liver: Hepatocholangioma										
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/98 (0%)	0/49 (0%) Mean 0%	SD 0%		
*Liver: Ito Cell Tumor Benign		0/50 (/0//)				0/40 (00/)	0/40 (00/)			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/98 (0%)	0/49 (0%) Mean 0%	SD 0%		
*Liver: Mast Cell Tumor Maligna										
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/98 (0%)	0/49 (0%) Mean 0%	SD 0%		
*Liver: Plasma Cell Tumor Malig	nant									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/98 (0%)	0/49 (0%) Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER **Page:** 199

			Male Female				0/49 (0%)       0/49 (0%)         Total       0/98 (0%)       Mean 0%       Si         5/50 (10%)       3/50 (6%)         Total       8/100 (8%)       Mean 8%       SD         7/50 (14%)       2/50 (4%)         Total       9/100 (9%)       Mean 9%       SD         11/50 (22%)       5/50 (10%)         Total       16/100 (16%)       Mean 16%       SD         0/50 (0%)       0/50 (0%)       Mean 0%       Si         Total       0/100 (0%)       Mean 0%       Si		
*Liver: Sarcoma									
		0/50 (0%)	0/50 (0%)			()	(/		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%	
*Lung: Alveolar/Bronchiolar Ac	lenoma								
		6/50 (12%)	13/50 (26%)			` '	` ,		
Overall Incidence	Total	19/100 (19%)	Mean 19%	SD 9.9%	Total	8/100 (8%)	Mean 8%	SD 2.83%	
*Lung: Alveolar/Bronchiolar Ca	arcinoma	9/50 (18%)	7/50 (14%)			7/50 (149/)	2/50 (4%)		
Overall Incidence	Total	16/100 (16%)	Mean 16%	SD 2.83%	Total	` '	` ,	SD 7.07%	
*Lung: Alveolar/Bronchiolar Ca		reolar/Bronchiolar Adenor 14/50 (28%)				11/50 (22%)	5/50 (10%)		
Overall Incidence	Total	33/100 (33%)	Mean 33%	SD 7.07%	Total	, ,	` ,	SD 8.49%	
*Lung: Hemangiosarcoma									
		2/50 (4%)	0/50 (0%)			` ,	` ,		
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%	
*Lung: Plasma Cell Tumor Mali	gnant								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

#Lymph Node:

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

#Lymph Node, Mediastinal: Mast Cell Tumor Malignant

#Lymph Node, Mandibular: Hemangiosarcoma

#Lymph Node, Mandibular: Mast Cell Tumor Malignant

#Lymph Node, Mandibular: Plasma Cell Tumor Malignant

#Lymph Node, Bronchial: Hemangiosarcoma

Length of Study: CHRONIC

**Plasma Cell Tumor Malignant** 

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Male **Female** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0%

Total

0/50

0/100 (0%)

(0%)

0/50

(0%)

SD 0%

Mean 0%

Page: 200

Report Date: 06/05/2013

Total

Total

Total

Total

Total

Total

0/50

0/100 (0%)

(0%)

0/50

Mean 0%

(0%)

SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Page: 201

			Male		0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD  0/50 (0%) 1/50 (2%) Total 1/100 (1%) Mean 1% SD 1			
#Lymph Node, Mesenteric: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	05 00/		` '	` ,	05 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	l otal	0/100 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Plasma Cell Tumor Malignan	t							
Overall Institutes	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	` '	` '	CD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	ı otal	0/100 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoma								
		0/50 (0%)	0/50 (0%)			` '	` ,	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		, ,		SD 0%
#Mammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)			, ,	` '	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			` '	` ,	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Mammary Gland: Fibroadenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 202

			Male				Female				
#Mammary Gland: Fibroma, Fibroadenoma or Adenoma											
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Mammary Gland: Fibroma, Fibroadenoma	a, Carcinoma, or	Adenoma									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%			
#Mesentery: Hemangioma		-/									
O	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	0/50 (0%)	0/50 (0%)	00, 00/			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Mesentery: Hemangiosarcoma											
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%			
	10tai	0/100 (0%)			10tai	1/100 (1%)		SD 1.41%			
#Mesentery: Lipoma											
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Mesentery: Sarcoma											
		0/50 (0%)	0/50 (0%)	25 22/		0/50 (0%)	0/50 (0%)	00.00			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Report Date: 06/05/2013

Page: 203

			Male			0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD (0%)  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD (0%)  Total 0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD (0%)  0/50 (0%) 0/50 (0%)		
*Nose: Adenoma								
O	<b>T</b> -1-1	0/50 (0%)	0/50 (0%)	OD 00/	Tatal	()	(/	00.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	l otal	0/99 (0%)	Mean 0%	SD 0%
*Nose: Hemangiosarcoma								
		1/50 (2%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/99 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Papilloma Squamous o	a, Tongue, Phar	ynx, Tooth, Gingiva):						
		0/50 (0%)	0/50 (0%)			` ,	` '	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		, ,		SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcin	a, Tongue, Phar							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcin		ynx, Tooth, Gingiva): Squamous, or Papilloma 0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Oral Mucosa: Squamous Cell Carcin	oma	0/50 (001)	0/50 (05)			0/50 (00)	0(50 (00))	
	<b>-</b>	0/50 (0%)	0/50 (0%)	<b>OD</b> 00/	<b>-</b>	` '	` '	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	l otal	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 204

Report Date: 06/05/2013

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Ovary: Choriocarcinoma 0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% \*Ovary: Cystadenocarcinoma 0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% \*Ovary: Cystadenoma 3/49 (6%)1/50 (2%)**Overall Incidence** Total 4/99 (4.04%) Mean 4.06% SD 2.92% ..... \*Ovary: **Granulosa Cell Tumor Benign** 0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% \*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS 0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% \*Ovary: Hemangioma 0/49 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% 0/99 (0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Page: 205

Mean 0%

SD 0%

Report Date: 06/05/2013

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Male **Female** \*Ovary: Hemangiosarcoma 0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% ..... \*Ovary: Luteoma 0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% \*Ovary: **Plasma Cell Tumor Malignant** 0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% ..... \*Ovary: Sarcoma 0/49 (0%)0/50 (0%)**Overall Incidence** SD 0% Total 0/99 (0%) Mean 0% \*Ovary: Teratoma Benign 0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% **Teratoma Malignant** 0/49 (0%)0/50 (0%)

Total

0/99 (0%)

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 206

			Male				Female	
*Ovary: Tubulostromal Adenom	na					0/40 (00%)	0/50 (00/)	
Overall Incidence					Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Yolk Sac Carcinoma								
Overall Incidence					Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma		0/40 (00/)	0/50 (00/)			0/40 (00)	0/40 /00/	
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/97 (0%)	0/49 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma or Adenoma	a	0/40 (00/)	0/50 (09/)			0/40 (00/)	0/40 //00/)	
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/97 (0%)	0/49 (0%) Mean 0%	SD 0%
*Pituitary Gland: Pars Dis Adenoma		ied Site:						
Overall Incidence	Total	0/47 (0%) 0/97 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	4/50 (8%) 6/99 (6.06%)	2/49 (4%) Mean 6.04%	SD 2.77%
*Pituitary Gland: Pars Dis		ied Site:			•••••			
Overall Incidence	Total	0/47 (0%) 0/97 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Page: 207

Report Date: 06/05/2013

Route: ORAL Vehicle: WATER

			Male				Female	
*Pituitary Gland: Pars Di Carcinoma or Adenom		fied Site:						
		0/47 (0%)	0/50 (0%)			4/50 (8%)	2/49 (4%)	
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%	Total	6/99 (6.06%)	Mean 6.04%	SD 2.77%
*Pituitary Gland: Pars Int Adenoma								
		0/47 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Int Carcinoma or Adenom	termedia:	0/47 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/97 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
Salivary Glands: Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenom								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Salivary Glands: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 208

Mean 0%

SD 0%

Report Date: 06/05/2013

			Male				Female	
*Salivary Glands: Mast Cell Tumor Malignant								
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	SD 0%	Total	0/50 (0%)	0/48 (0%) Mean 0%	CD 00/
	Total	0/100 (0%)	Mean 0%		Total	0/98 (0%)		SD 0%
*Salivary Glands: Myxoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma								
		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skeletal Muscle: Rhabdomyosarcoma								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma or Rhab	odomyoma						•••••	
•	•	1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	

SD 1.41%

Mean 1%

Total

0/100 (0%)

Total

1/100 (1%)

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE Strain: B6C3F1 **Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Page: 209

Report Date: 06/05/2013

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Skeletal Muscle:** Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% #Skin: **Basal Cell Carcinoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% Total #Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% Total ...... #Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/100 (0%) Overall Incidence Total 0/100 (0%) Mean 0% SD 0% Total Mean 0% SD 0% #Skin:

SD 0%

SD 0%

0/50

2/50

6/100 (6%)

(4%)

0/100 (0%)

Total

Total

0/50

4/50

(0%)

(8%)Mean 6%

SD 0%

SD 2.83%

Mean 0%

Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma,

Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma

0/50

0/100 (0%)

2/100 (2%)

(0%)

(2%)

0/50

1/50

Mean 0%

Mean 2%

(0%)

(2%)

Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma

Total

Total

**Overall Incidence** 

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

ed Control Animal Groups Report Date: 06/05/2013
ORAL

Page: 210

			Male				Female	
#Skin: Fibrosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Fibrosarcoma, Sarcoma	ı, Myxosarcoma	, or Fibrous Histiocytoma				0(50 (40))	4/50 (00/)	
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	2/50 (4%) 6/100 (6%)	4/50 (8%) Mean 6%	SD 2.83%
#Skin: Fibrous Histiocytoma		1/50 (2%)	4/50 (20/)			0/50 (0%)	2/50 (60/)	
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 3/100 (3%)	3/50 (6%) Mean 3%	SD 4.24%
#Skin: Granular Cell Tumor Be	nign	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Hemangioma		(20)	(20)					
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Hemangiosarcoma								
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 211

			Male				Female	
#Skin: Keratoacanthoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Lipoma								
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Liposarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Mast Cell Tumor Benign						4/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Skin: Mast Cell Tumor Malignant								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Melanoma Benign								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 212

Report Date: 06/05/2013

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

		Male				Female						
#Skin: Melanoma Malignant												
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)						
Total	` '	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%					
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)						
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%					
nnoma benign	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)						
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%					
	alignant or NOS)				0/50 (0%)	3/50 (6%)						
Total	0/100 (0%)	Mean 0%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 4.24%					
	Schwannoma (benign, ma	lignant or NOS)										
<b>.</b>	` ,	` '	<b>OD</b> 00/	<b>T</b>	` '	` '	00 4 0 407					
	` '				` '		SD 4.24%					
	0/50 (09/)	0/50 /09/			0/50 (09/)	0/50 (0%)						
Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%					
	Total  nnoma benign  Total  chwannoma (m  Total  urofibroma, or S	Total 0/100 (0%)  0/50 (0%)  Total 0/100 (0%)  nnoma benign  0/50 (0%)  Total 0/100 (0%)  chwannoma (malignant or NOS)  0/50 (0%)  Total 0/100 (0%)  urofibroma, or Schwannoma (benign, ma  0/50 (0%)  Total 0/100 (0%)  0/50 (0%)	0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%  nnoma benign 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%  chwannoma (malignant or NOS) 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%  urofibroma, or Schwannoma (benign, malignant or NOS) 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%	O/50 (0%) O/50 (0%)   Total O/100 (0%)   Mean 0%   SD 0%	Total 0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total     O/50 (0%) 0/50 (0%) SD 0% Total    Total 0/100 (0%) Mean 0% SD 0% Total    O/50 (0%) 0/50 (0%) SD 0% Total    O/50 (0%) 0/50 (0%) SD 0% Total    Chwannoma (malignant or NOS) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total    O/50 (0%) 0/50 (0%) SD 0% Total    O/50 (0%) 0/50 (0%) SD 0% Total    O/50 (0%) 0/50 (0%) SD 0% Total	Total 0/50 (0%) 0/50 (0%) SD 0% Total 0/100 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  Total 0/100 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  **Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  **Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  **Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  **Chwannoma (malignant or NOS)  **O/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 3/100 (3%)  **Total 0/100 (0%) Mean 0% SD 0% Total 3/100 (3%)  **Total 0/100 (0%) Mean 0% SD 0% Total 3/100 (3%)	0/50 (0%) 0/50 (0%)   0/50 (0%)   Nean 0%   SD 0%   Total   0/100 (0%)   Mean 0%   Nean 0%					

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Page: 213

Report Date: 06/05/2013

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male		Female			
#Skin: Sarcoma		0/50 (00/)	0/50 (00/)			0/50 (40/)	4/50 (00()	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%
#Skin: Schwannoma Benign	•••••	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Schwannoma Malignant								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 3/100 (3%)	3/50 (6%) Mean 3%	SD 4.24%
#Skin: Squamous Cell Carcinoma or Carcinoma	Basal Cell (	Carcinoma, Basosquamou	us Tumor (malignant	or NOS),				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma o							0/50 (00()	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 214

	Male					Female					
#Skin: Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma  0/50 (0%) 0/50 (0%)  0/50 (0%)  0/50 (0%)  0/50 (0%)											
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Skin: Squamous Cell Papilloma	, Papilloma, o		0/50 (00/)			0(50 (00))	0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
#Skin: Sebaceous Gland: Adenoma											
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Spinal Cord: Hemangiosarcoma											
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
*Spleen: Hemangioma			(00)								
Overall Incidence	Total	0/46 (0%) 0/96 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/46 (0%) 0/95 (0%)	0/49 (0%) Mean 0%	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

\*Spleen:

\*Spleen:

\*Spleen:

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Hemangiosarcoma

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

**Overall Incidence** 

**Mast Cell Tumor Malignant** 

**Plasma Cell Tumor Malignant** 

#Stomach, Forestomach: Squamous Cell Carcinoma Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Male **Female** 2/50 (4%)1/46 (2%)0/49 (0%)Mean 3.09% SD 1.29% Total 1/95 (1.05%) Mean 1.09% SD 1.54% 0/50 (0%)0/46 (0%)0/49 (0%)Mean 0% SD 0% Total 0/95 (0%) Mean 0% SD 0% 0/50 (0%)0/46 (0%)0/49 (0%)Mean 0% SD 0% Total 0/95 (0%) Mean 0% SD 0%

0/50

0/100 (0%)

1/100 (1%)

Total

Total

(0%)

0/50

(0%)

Mean 0%

Mean 1%

SD 0%

SD 1.41%

Page: 215

Report Date: 06/05/2013

#Stomach, Forestomach: Squamous Cell Carcinoma	or Papilloma S	Squamous						
		0/50 (0%)	0/50 (0%)	25		0/50 (0%)	1/50 (2%)	05 4 4404
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Stomach, Forestomach: Squamous Cell Papilloma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	

SD 0%

SD 0%

Total

Total

Total

Total

Total

1/46

3/96 (3.12%)

0/46

0/96 (0%)

0/46

0/96 (0%)

0/50

0/100 (0%)

0/100 (0%)

(2%)

(0%)

(0%)

(0%)

0/50

Mean 0%

Mean 0%

(0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 216 Report Date: 06/05/2013

			Male				Female	
#Stomach, Glandular: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma	•••••							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma or Adenoma		0/50 (00/)	0/50 (00)			0/50 (001)	0/50 (00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Testes: Adenoma		0/50 (0%)	4/50 (00)					
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%				
*Testes: Hemangioma		0/50 (0%)	0/50 (00/)					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Thymus: Neoplasm NOS								
Overall Incidence	Total	0/41 (0%) 0/86 (0%)	0/45 (0%) Mean 0%	SD 0%	Total	0/45 (0%) 0/95 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 217

			Male				Female	
*Thymus: Thymoma Benign		0/41 (0%)	0/45 (0%)			0/45 (0%)	0/50 (09/)	
Overall Incidence	Total	0/41 (0%) 0/86 (0%)	0/45 (0%) Mean 0%	SD 0%	Total	0/45 (0%) 0/95 (0%)	0/50 (0%) Mean 0%	SD 0%
*Thymus: Thymoma Malignant								
Overall Incidence	Total	0/41 (0%) 0/86 (0%)	0/45 (0%) Mean 0%	SD 0%	Total	0/45 (0%) 0/95 (0%)	0/50 (0%) Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Maligna	ant, NOS	0/41 (0%)	0/45 (0%)			0/45 (0%)	0/50 (0%)	
Overall Incidence	Total	0/86 (0%)	Mean 0%	SD 0%	Total	0/95 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma		0/49 (0%)	0/50 (0%)			0/48 (0%)	0/49 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/97 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma								
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/97 (0%)	0/49 (0%) Mean 0%	SD 0%
*Thyroid Gland: Follicular Ce Adenoma								
Overall Incidence	Total	1/49 (2%) 2/99 (2.02%)	1/50 (2%) Mean 2.02%	SD 0.03%	Total	0/48 (0%) 0/97 (0%)	0/49 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

Page: 218

			Male		0/48 (0%) 0/49 (0%)					
*Thyroid Gland: Follicular Ce Carcinoma	II:	0/49 (0%) 0/50 (0%) 0/48 (0		0/40 (00/)	(2)					
Overall Incidence	Total	0/49 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	()	` '	SD 0%		
*Thyroid Gland: Follicular Ce Carcinoma or Adenoma	II:	1/49 (2%)	1/50 (2%)			0/48 (0%)	0/40 (0%)			
Overall Incidence	Total	2/99 (2.02%)	Mean 2.02%	SD 0.03%	Total	` '	` '	SD 0%		
#Tissue NOS: Fibrosarcoma		•••••								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
#Tissue NOS: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Tissue NOS: Plasma Cell Tumor Maligna	ant									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
#Tissue NOS: Sarcoma										
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Vehicle: WATER

or Selected Control Animal Groups

Route: ORAL

·

Page: 219

Report Date: 06/05/2013

Length of Study: CHRONIC

Contract/Lab: All Laboratories

		Male				Female	
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
	` '		SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
a							
<b>-</b>	` '	` '	00.00/	<b>-</b>	` '	` '	00.00/
	, ,				0/100 (0%)	Mean 0%	SD 0%
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
	, ,	` ,			` '	0/50 (0%)	
Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
	0/45 (0%)	0/50 (0%)			0/44 (0%)	0/50 (0%)	
Total	` '	` ,	SD 0%	Total	` '	` ,	SD 0%
	Total  Total  Total  Total	Total 0/100 (0%)  na or Papilloma Squamous 0/50 (0%) Total 0/100 (0%)  a 0/50 (0%) Total 0/100 (0%)  Total 0/100 (0%)  Total 0/100 (0%)  Total 0/50 (0%) Total 1/100 (1%)	0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%  na or Papilloma Squamous 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%  a 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%  Total 0/100 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%  Total 0/50 (0%) 1/50 (2%) Total 1/100 (1%) Mean 1%	0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0%  na or Papilloma Squamous 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0%  a  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0%  Total 0/100 (0%) Mean 0% SD 0%  Total 0/100 (0%) Mean 0% SD 0%  Total 0/50 (0%) 0/50 (0%) Total 1/100 (1%) Mean 1% SD 1.41%	Total 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total  na or Papilloma Squamous 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total  a 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total  Total 0/100 (0%) 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0% Total  Total 0/100 (0%) Mean 0% SD 0% Total  Total 0/100 (0%) Mean 0% SD 0% Total	O/50 (0%)   O/50 (0%)   O/50 (0%)   O/50 (0%)   O/100 (0%)	O/50 (0%)   O/50

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date: 06/05/2013

Page: 220

Species: MICE Strain: B6C3F1 Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female         0/50 (0%)       Mean 0%       SD 0%         0/50 (0%)       Mean 1%       SD 1.41%         0/50 (0%)       Mean 0%       SD 0%         1/50 (2%)       Mean 1%       SD 1.41%         0/50 (0%)       Mean 0%       SD 0%         0/50 (0%)       Mean 0%       SD 0%	
*Urinary Bladder: Plasma Cell Tumor Mal	lignant							
		0/45 (0%)	0/50 (0%)			0/44 (0%)	` '	
Overall Incidence	Total	0/95 (0%)	Mean 0%	SD 0%	Total	0/94 (0%)	Mean 0%	SD 0%
tUterus: Adenoma								
						1/50 (2%)	` '	
Overall Incidence					Total	1/100 (1%)	Mean 1%	SD 1.41%
#Uterus: Carcinoma								
						0/50 (0%)	` '	
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%
#Uterus: Hemangiosarcoma								
						0/50 (0%)	` '	
Overall Incidence					Total	1/100 (1%)	Mean 1%	SD 1.41%
#Uterus: Leiomyoma								
•						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%
#Uterus: Leiomyosarcoma								
						0/50 (0%)	` '	
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Page: 221

Report Date: 06/05/2013

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Uterus: Polyp Stromal** 2/50 (4%)4/50 (8%)**Overall Incidence** Total 6/100 (6%) Mean 6% SD 2.83% **#Uterus:** Sarcoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% #Uterus: Sarcoma Stromal 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% ..... #Uterus: Sarcoma Stromal or Polyp Stromal 2/50 (4%)4/50 (8%) **Overall Incidence** Total 6/100 (6%) Mean 6% SD 2.83% #Vagina: Liposarcoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% #Zymbal's Gland: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% 0/100 (0%) Mean 0% SD 0% 0/100 (0%) Total

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 222

			Male		Female  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD 0%		
#Zymbal's Gland: Carcinoma or Adenoma							
		0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	` ,		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Page: 223

Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

# Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Southern Research Institute	058813308	12/13/04	729	50(1)	30(665)	54.9	Trimethylolpropane triacrylate
					Female		
Southern Research Institute	058813308	12/13/04	732	50(1)	39(712)	66.6	Trimethylolpropane triacrylate

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Gloups

Page: 224

			Male				Female	
#All Organs: Benign Tumors								
-		37/50 (74%)				41/50 (82%)		
Overall Incidence	Total	37/50 (74%)	Mean 74%	SD 0%	Total	41/50 (82%)	Mean 82%	SD 0%
#All Organs: Malignant Tumors		00/50 (700()				00/50 /700/		
Overall Incidence	Total	38/50 (76%) 38/50 (76%)	Mean 76%	SD 0%	Total	38/50 (76%) 38/50 (76%)	Mean 76%	SD 0%
#All Organs: Malignant and Benign Tu					•••••			
3 4 4 4 5		46/50 (92%)				47/50 (94%)		
Overall Incidence	Total	46/50 (92%)	Mean 92%	SD 0%	Total	47/50 (94%)	Mean 94%	SD 0%
#All Organs: Hemangioma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma								
_		6/50 (12%)				2/50 (4%)		
Overall Incidence	Total	6/50 (12%)	Mean 12%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#All Organs: Hemangiosarcoma or Hel	mangioma	C/EO (420/)				2/50 /40/\		
Overall Incidence	Total	6/50 (12%) 6/50 (12%)	Mean 12%	SD 0%	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ACETONE

Page: 225

			Male			2/50 (4%) 2/50 (4%) Mean 4% SD 0%  20/50 (40%) 20/50 (40%) Mean 40% SD 0%  0/50 (0%) 0/50 (0%) Mean 0% SD 0%  0/50 (0%) 0/50 (0%) Mean 0% SD 0%			
#All Organs: Histiocytic Sarcoma									
		0/50 (0%)				2/50 (4%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
#All Organs: Malignant Lymphoma: Hist	iocytic, Lym	phocytic, Mixed, NOS, o 2/50 (4%)	r Undifferentiated Ce	ell Type		20/50 (40%)			
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	` '	Mean 40%	SD 0%	
#All Organs: Mesothelioma: Benign									
		0/50 (0%)				` ,			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#All Organs: Mesothelioma: Benign, Ma	lignant, NOS	0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	` ,	Mean 0%	SD 0%	
#All Organs: Mesothelioma: Malignant									
		0/50 (0%)				` ,			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#All Organs: Osteoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Page: 226

Report Date: 06/05/2013

SD 0%

Mean 4%

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

Male **Female** #All Organs: Osteosarcoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% ..... #All Organs: Osteosarcoma or Osteoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% \*Adrenal Cortex: Adenoma 6/50 (12%)0/50 (0%)**Overall Incidence** Total 6/50 (12%) Mean 12% SD 0% Total 0/50 (0%) Mean 0% SD 0% ...... \*Adrenal Cortex: **Plasma Cell Tumor Malignant** 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% \*Adrenal Medulla: Pheochromocytoma Benign 0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/49 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% ..... \*Adrenal Medulla: **Pheochromocytoma Malignant** 0/49 (0%)2/50 (4%)

SD 0%

Total

2/50 (4%)

Total

0/49 (0%)

Mean 0%

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 227

				Male			0/50 (0%) al 0/50 (0%) Mean 0% SD 0%  0/50 (0%) al 0/50 (0%) Mean 0% SD 0%  0/50 (0%) Mean 0% SD 0%  0/50 (0%) SD 0%				
Overall Incidence	Total	0/49 (0%)		Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%		
#Blood Vessel: Hemangioma		0/50	(0%)				0/50 (00/)				
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%		
*Bone Marrow: Hemangioma		0/50	(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	` ,	Mean 0%	SD 0%	Total	0/50 (0%)		SD 0%		
*Bone Marrow: Hemangiosarcoma			(2%)								
Overall Incidence	Total	1/50 (2%)	` ,	Mean 2%	SD 0%	Total	0/50 (0%)		SD 0%		
*Bone Marrow: Mast Cell Tumor Malignant											
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	` '	Mean 0%	SD 0%		
*Bone Marrow: Plasma Cell Tumor Maligna	ant	0/50	(0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	(-,-,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 228

		Male		0/50 (0%) Total 0/50 (0%) Mean 0% SD 0%			
	0/50 (0%)				` '		
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
	0/50 (0%)				` '		
	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
	2/22 (22)				2/22 (221)		
T-1-1	, ,	M 00/	OD 00/	T-1-1	` '	Maran 00/	00.00/
	` '				, ,		SD 0%
	0/50 (00/)				0/50 (09/)		
Total	0/50 (0%)	Mean 0%	SD 0%		0/50 (0%)		
	0/50 (0%)				0/50 (0%)		
Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
a	0/50 (0%)				0/50 (0%)		
Total	, ,	Mean 0%	SD 0%	Total	, ,	Mean 0%	SD 0%
	Total Total	Total 0/50 (0%)  0/50 (0%)  Total 0/50 (0%)  0/50 (0%)  Total 0/50 (0%)  Total 0/50 (0%)  Total 0/50 (0%)  Total 0/50 (0%)  4  0/50 (0%)	0/50 (0%) Total 0/50 (0%) Mean 0%  Total 0/50 (0%) Mean 0%  0/50 (0%) Total 0/50 (0%) Mean 0%	0/50 (0%)       Total     0/50 (0%)     Mean 0%     SD 0%       Total     0/50 (0%)     Mean 0%     SD 0%	Total 0/50 (0%) Mean 0% SD 0% Total    Total 0/50 (0%)	Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%)	Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%  Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 229

			Male		0/50 (0%) % Total 0/50 (0%) Mean 0% SD 0  0/50 (0%) % Total 0/50 (0%) Mean 0% SD 0  0/50 (0%)			
#Bone: Sarcoma		0/50 (0%)				` '		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Brain: Granular Cell Tumor Beni	ign	0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%		0/50 (0%)		SD 0%
*Brain: Meningioma Benign		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%		0/50 (0%)		SD 0%
*Brain: Meningioma Malignant		0/50 (0%)						
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%		0/50 (0%)		SD 0%
*Brain: Meningioma: Benign, Mal		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma Malig	nant	4/50 (20/)				0/50 (09/)		
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 230 Report Date: 06/05/2013

			Male				Female	
*Brain: Oligodendroglioma, Gliom	a, or Astrocy	toma						
Overall Incidence	Total	1/50 (2° 1/50 (2%)	%) Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Brain: Schwannoma Malignant								
Overall Incidence	Total	0/50 (0° 0/50 (0%)	%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangioma		0/50 (0 <sup>4</sup>	27.)			0/49 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangiosarcoma	Total	0/50 (0º 0/50 (0%)		SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
#Coagulating Gland: Granular Cell Tumor		 0/50 (0 <sup>4</sup>				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Coagulating Gland: Sarcoma		0/50 (0 <sup>4</sup>	ov.)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	%) Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 231

			Male			Female			
#Esophagus: Squamous Cell Carcinoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Eye: Melanoma Malignant		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Harderian Gland: Adenoma									
Overall Incidence	Total	8/50 (16%) 8/50 (16%)	Mean 16%	SD 0%	Total	5/50 (10%) 5/50 (10%)	Mean 10%	SD 0%	
#Harderian Gland: Carcinoma		3/50 (6%)				2/50 (4%)			
Overall Incidence	Total	3/50 (6%)	Mean 6%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
#Harderian Gland: Carcinoma or Adenoma									
Overall Incidence	Total	11/50 (22%) 11/50 (22%)	Mean 22%	SD 0%	Total	7/50 (14%) 7/50 (14%)	Mean 14%	SD 0%	
*Heart: Hemangiosarcoma									
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 232

			Male			Female			
#Intestine Large: Cecum: Adenoma									
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
	10lai	1/50 (2%)	iviedii 276		10lai	0/30 (0%)	Wear 076	3D 0%	
#Intestine Large: Cecum: Carcinoma									
		0/50 (0%)	• • • • • • • • • • • • • • • • • • • •	<b>05 6</b> 0/		0/50 (0%)		05	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Large: Cecum: Carcinoma or Adenoma		4/50 (00)				0/50 (00/)			
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
					10tai	0/30 (0/8)			
#Intestine Large: Cecum: Leiomyoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Large: Cecum: Leiomyosarcoma									
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Large: Colon/Rect Leiomyosarcoma						0/50 /00/			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Moon 09/	SD 0%	
Overall incluence	Total	0/50 (0%)	iviean 0%	3D 0%	าบเลเ	U/OU (U%)	Mean 0%	3D 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 233

				Male	Female				
#Intestine Small: Duodenum: Adenoma									
			(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Carcinoma									
			(0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Intestine Small: Duodenum: Leiomyosarcoma		- 1							
Occupation of James	T-1-1		(0%)	M 00/	OD 00/	T-1-1	0/50 (0%)	M 00/	OD 00/
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Polyp Adenomatous		- 1							
Overall Incidence	Tatal		(0%)	Mann 00/	CD 00/	Tatal	0/50 (0%)	Mana 00/	SD 0%
Overali incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	
#Intestine Small: Ileum: Adenoma									
			(0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Carcinoma									
			(0%)	••	05.00		0/50 (0%)		00.00
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 234

				Male			Female			
#Intestine Small: Ileum: Polyp Adenomatous		0/50 (0	0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean	0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Jejunum: Adenoma		0/50 /6	20/)				0/50 (00/)			
Overall Incidence	Total	0/50 (0%)	0%) Mean	0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Jejunum: Carcinoma			40/)				0/50 (00/)			
Overall Incidence	Total	2/50 (4%)	4%) Mean	4%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Jejunum: Hemangiosarcoma		0/50 (0	0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean	0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Jejunum: Leiomyosarcoma										
Overall Incidence	Total	0/50 (0 0/50 (0%)	0%) Mean	0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Intestine Small: Site Unspec Adenoma		0/50 /3	20()				0/50 (001)			
Overall Incidence	Total	0/50 (0 0/50 (0%)	0%) Mean	0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 235

			Male				Female	
#Intestine Small: Site Unspe Carcinoma	cified:							
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Intestine Small: Site Unspe Carcinoma or Adenoma	cified:							
Overall Incidence	Total	2/50 (4%) 2/50 (4%)	Mean 4%	SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Intestine Small: Site Unspe Hemangiosarcoma	cified:	0/50 (00/)				0/50 (09/)		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe Leiomyosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspe Polyp Adenomatous							•••••	
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma		0/50 (00/)				2/40 /49/		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	2/49 (4%) 2/49 (4.08%)	Mean 4.08%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Page: 236

Report Date: 06/05/2013

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

			Male			Female			
*Islets, Pancreatic: Carcinoma									
		0/50 (0%)				0/49 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
*Islets, Pancreatic: Carcinoma or Adenoma									
		0/50 (0%)				2/49 (4%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/49 (4.08%)	Mean 4.08%	SD 0%	
*Kidney: Pelvis and Transitio Carcinoma	onal Epitheliu								
		0/48 (0%)				0/49 (0%)			
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
*Kidney: Pelvis and Transitio Carcinoma or Adenoma									
		0/48 (0%)				0/49 (0%)			
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Adenoma									
		2/48 (4%)				0/49 (0%)			
Overall Incidence	Total	2/48 (4.17%)	Mean 4.17%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Carcinoma									
		0/48 (0%)				0/49 (0%)			
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 237

Report Date: 06/05/2013

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ACETONE

			Male			Female			
*Kidney: Renal Tubule: Carcinoma or Adenoma	Taral	2/48 (4%)	Maran 4.470/	OD 004	Total	0/49 (0%)	M 00/	0D 0V	
Overall Incidence	Total	2/48 (4.17%)	Mean 4.17%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Hemangioma		0/40 (004)				0/40 (00/)			
Overall Incidence	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Hemangiosarcoma		0/48 (0%)				0/49 (0%)			
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Plasma Cell Tumor Maligna		0/48 (0%)				0/49 (0%)			
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Sarcoma									
		0/48 (0%)				0/49 (0%)			
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
*Liver: Hemangioma		0/50 /02/				0/50 (00/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
Overall illelidelide	i Ulai	0/30 (0/0)	Mean 070	JD 070	i Ulai		IVICALI U70		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 238

			Male			Female			
*Liver: Hemangiosarcoma									
•		2/50 (4%)				0/50 (0%)			
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Liver: Hepatoblastoma									
·		5/50 (10%)				0/50 (0%)			
Overall Incidence	Total	5/50 (10%)	Mean 10%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Liver: Hepatocellular Adenoma									
		34/50 (68%)				34/50 (68%)			
Overall Incidence	Total	34/50 (68%)	Mean 68%	SD 0%	Total	34/50 (68%)	Mean 68%	SD 0%	
*Liver: Hepatocellular Carcinoma									
Overall Incidence	Total	22/50 (44%) 22/50 (44%)	Mean 44%	SD 0%	Total	12/50 (24%) 12/50 (24%)	Mean 24%	SD 0%	
*Liver:									
Hepatocellular Carcinoma	or Hepatobla								
		26/50 (52%)				12/50 (24%)			
Overall Incidence	Total	26/50 (52%)	Mean 52%	SD 0%	Total	12/50 (24%)	Mean 24%	SD 0%	
*Liver: Hepatocellular Carcinoma						37/50 (74%)			
Overall Incidence	Total	37/50 (74%)	Mean 74%	SD 0%	Total	37/50 (74%)	Mean 74%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

SKIN \_\_\_\_

Page: 239

			Male			Female					
*Liver: Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma											
•	•	38/50 (76%)				37/50 (74%)					
Overall Incidence	Total	38/50 (76%)	Mean 76%	SD 0%	Total	37/50 (74%)	Mean 74%	SD 0%			
*Liver: Hepatocholangiocarcinoma											
		2/50 (4%)				0/50 (0%)					
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Liver: Hepatocholangioma											
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Liver: Ito Cell Tumor Benign		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Liver: Mast Cell Tumor Malignant											
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Liver: Plasma Cell Tumor Malignaı		0/50 (0%)				0/50 (0%)					
Overell Incidence	Total	` '	Maan OO/	CD 00/	Total	` ,	Maan 00/	CD 00/			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 240

			Male			Female			
*Liver: Sarcoma									
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
			······						
*Lung: Alveolar/Bronchiolar Ad	lenoma								
		1/50 (2%)				3/50 (6%)			
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%	
*Lung: Alveolar/Bronchiolar Ca	rcinoma								
		12/50 (24%)				2/50 (4%)			
Overall Incidence	Total	12/50 (24%)	Mean 24%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	
*Lung: Alveolar/Bronchiolar Ca	rcinoma or Alve	eolar/Bronchiolar Adenoi 13/50 (26%)	ma			5/50 (10%)			
Overall Incidence	Total	13/50 (26%)	Mean 26%	SD 0%	Total	5/50 (10%)	Mean 10%	SD 0%	
*Lung: Hemangiosarcoma									
		0/50 (0%)	••	<b>OD</b> .00/		0/50 (0%)	• • • • • • • • • • • • • • • • • • • •	00.00	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
*Lung: Plasma Cell Tumor Mali	gnant								
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 241

				Male			Female			
#Lymph Node: Plasma Cell Tumor Malignar	nt									
_		,	0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Λ	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Lymph Node, Bronchial: Hemangiosarcoma										
		,	0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Λ	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Lymph Node, Mandibular: Hemangiosarcoma										
Occupation of James	T-1-1	,	0%)	4 00/	OD 00/	Tarat	0/50 (0%)	M 00/	OD 00/	
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Lymph Node, Mandibular: Mast Cell Tumor Malignant		0/50 //	20()				0/50 (00/)			
Overall Incidence	Total	0/50 (0 0/50 (0%)	0%) •	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
		` '								
#Lymph Node, Mandibular: Plasma Cell Tumor Malignar	nt									
		•	0%)	_			0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	٨	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Lymph Node, Mediastinal: Mast Cell Tumor Malignant		2/-2					(201)			
Overell Insidence	Tatal	,	0%)	A 00/	CD 00/	Tatal	0/50 (0%)	Mann 00/	CD 00/	
Overall Incidence	Total	0/50 (0%)	ŗ	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 242

				Male			Female			
#Lymph Node, Mesenteric: Hemangiosarcoma		,								
Overall Incidence	Total	1/50 1/50 (2%)	(2%)	Mean 2%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Lymph Node, Mesenteric: Plasma Cell Tumor Maligna	ınt									
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Mammary Gland: Adenoma		0/50	(00()				0/50 (00/)			
Overall Incidence	Total	0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Mammary Gland: Carcinoma			(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	,	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Mammary Gland: Carcinoma or Adenoma										
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Mammary Gland: Fibroadenoma		0/5	(224)				(00)			
Overall Incidence	Total	0/50 0/50 (0%)	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 243

Report Date: 06/05/2013

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Strain: B6C3F1 Vehicle: ACETONE

			Male				Female				
#Mammary Gland: Fibroma, Fibroadenoma or Adenoma											
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Mammary Gland: Fibroma, Fibroadenom	na, Carcinoma, or	<b>Adenoma</b> 0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Mesentery: Hemangioma		(20)				(201)					
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Mesentery: Hemangiosarcoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Mesentery:											
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%			
#Mesentery: Sarcoma		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

SKIN

Report Date: 06/05/2013

Page: 244

			Male			0/50 (0%) tal 0/50 (0%) Mean 0% SD 0%					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Nose: Hemangiosarcoma		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Oral Cavity (Oral Mucosa Papilloma Squamous o	a, Tongue, Phary	nx, Tooth, Gingiva):				0/50 (00/)					
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	( ,	Mean 0%	SD 0%			
#Oral Cavity (Oral Mucosa Squamous Cell Carcino	a, Tongue, Phary					0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Oral Cavity (Oral Mucosa Squamous Cell Carcino	a, Tongue, Phary					0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Oral Mucosa: Squamous Cell Carcino	ma	0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ACETONE

Page: 245

	Male			Female	
*Ovary: Choriocarcinoma					
Overall Incidence		Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%
*Ovary: Cystadenocarcinoma					
Overall Incidence		Total	1/47 (2%) 1/47 (2.13%)	Mean 2.13%	SD 0%
*Ovary: Cystadenoma					
Overall Incidence		Total	1/47 (2%) 1/47 (2.13%)	Mean 2.13%	SD 0%
*Ovary: Granulosa Cell Tumor Benign			0/47 (00/)		
Overall Incidence		Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS					
Overall Incidence		Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%
*Ovary: Hemangioma					
Overall Incidence		Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 246

	Male			Female	
*Ovary: Hemangiosarcoma					
Overall Incidence		Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%
*Ovary: Luteoma					
Overall Incidence		Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%
*Ovary: Plasma Cell Tumor Malignant					
Overall Incidence		Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%
*Ovary: Sarcoma					
Overall Incidence		Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%
*Ovary: Teratoma Benign					
Overall Incidence		Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%
*Ovary: Teratoma Malignant					
Overall Incidence		Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 247

Report Date: 06/05/2013

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ACETONE

			Male				Female	
*Ovary: Tubulostromal Adenoma								
Overall Incidence					Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%
*Ovary: Yolk Sac Carcinoma								
Overall Incidence					Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%
*Pancreas: Carcinoma		•••••						
Overall Incidence	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%
*Pancreas: Carcinoma or Adenoma		1/50 (2%)				0/49 (0%)		
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Distali Adenoma			•••••			•••••		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	7/49 (14%) 7/49 (14.29%)	Mean 14.29%	SD 0%
*Pituitary Gland: Pars Distali Carcinoma								
		0/50 (0%)				0/49 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 248

	Male				Female					
*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma										
		0/50 (0%)				7/49 (14%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	7/49 (14.29%)	Mean 14.29%	SD 0%		
*Pituitary Gland: Pars Inter	media:									
		0/50 (0%)				0/49 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%		
*Pituitary Gland: Pars Inter Carcinoma or Adenoma										
		0/50 (0%)				0/49 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%		
*Salivary Glands: Adenoma										
		0/50 (0%)		05 00/		0/50 (0%)		22 22/		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Salivary Glands: Carcinoma or Adenoma										
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
*Salivary Glands: Hemangiosarcoma										
		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Animal Groups Report Date: 06/05/2013

Page: 249

			Male			Female			
*Salivary Glands: Mast Cell Tumor Malignar	nt			-					
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
*Salivary Glands: Myxoma		0/50 (00/)				0/50 (00/)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Seminal Vesicle: Adenoma		0/50 (0%)							
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%					
#Skeletal Muscle: Hemangiosarcoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skeletal Muscle: Rhabdomyosarcoma		0/50 (00()				0/50 (0%)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Skeletal Muscle: Rhabdomyosarcoma or R	thabdomyoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 250

Report Date: 06/05/2013

Route: SKIN

Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Skeletal Muscle: Sarcoma								
		0/50 (0%)				2/50 (4%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%
#Skin: Basal Cell Carcinoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma	or Basosquamou	s Tumor (malignant or N	ios)			0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
NOS), or Trichoepithel	lioma	oma, Basosquamous Tu	mor (benign, maligna	ant or		0/50 (0%)		
Overall Incidence	Tatal					` '		
Overall incluence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal or Sq. Cell Carci	inoma, Carcinoma	a, Basosq. Tumor (M or ratoacanthoma, Trichoel	B), Basal Cell Adeno		Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S Overall Incidence	inoma, Carcinoma Sq Papilloma, Ker Total	a, Basosq. Tumor (M or ratoacanthoma, Trichoel 1/50 (2%)	B), Basal Cell Adenor pithelioma Mean 2%	ma, SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%
#Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S Overall Incidence #Skin:	inoma, Carcinoma Sq Papilloma, Ker Total	a, Basosq. Tumor (M or ratoacanthoma, Trichoel 1/50 (2%)	B), Basal Cell Adenor pithelioma Mean 2%	ma, SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%
#Skin: Basal or Sq. Cell Carci Adenoma, Papilloma, S Overall Incidence #Skin:	inoma, Carcinoma Sq Papilloma, Ker Total	a, Basosq. Tumor (M or ratoacanthoma, Trichoel 1/50 (2%) 1/50 (2%)	B), Basal Cell Adenor pithelioma Mean 2%	ma, SD 0%	Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Report Date: 06/05/2013

Page: 251

Species: MICE Strain: B6C3F1

Vehicle: ACETONE

Length of Study: CHRONIC

			Male				Female		
#Skin: Fibrosarcoma		0/50 (0%)		00.00		3/50 (6%)		05.00	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/50 (6%)	Mean 6%	SD 0%	
#Skin: Fibrosarcoma, Sarcoma,	Myxosarcoma,	, or Fibrous Histiocytoma 0/50 (0%)				4/50 (8%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	4/50 (8%)	Mean 8%	SD 0%	
#Skin: Fibrous Histiocytoma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Granular Cell Tumor Ben		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Hemangioma		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Skin: Hemangiosarcoma		2/50 (4%)				2/50 (4%)			
Overall Incidence	Total	2/50 (4%)	Mean 4%	SD 0%	Total	2/50 (4%)	Mean 4%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

r Incidence for Selected Control Animal Gro **Route:** SKIN Page: 252

Report Date: 06/05/2013

Strain: B6C3F1 Length of Study: CHRONIC Vehicle: ACETONE

			Male				Female	
#Skin: Keratoacanthoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Lipoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Mast Cell Tumor Benign		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Skin: Mast Cell Tumor Malignant								
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Skin: Melanoma Benign		0/50 (0%)				1/50 (2%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

nimal Groups Report Date: 06/05/2013

Page: 253

	Male					Female				
#Skin: Melanoma Malignant		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Neural Crest Tumor		0/50 (0%)				1/50 (2%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%		
#Skin: Neurofibroma or Schwar		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Neurofibrosarcoma or So	chwannoma (ma	alignant or NOS) 0/50 (0%)	•••••			0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Neurofibrosarcoma, Neu		chwannoma (benign, ma				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		
#Skin: Osteosarcoma		0/50 (0%)				0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Page: 254

Report Date: 06/05/2013

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Male **Female** #Skin: Sarcoma 0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 1/50 (2%) Mean 2% SD 0% ..... #Skin: Schwannoma Benign 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #Skin: **Schwannoma Malignant** 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% ..... #Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma (0%)0/50 (0%)0/50 0/50 (0%) 0/50 (0%) **Overall Incidence** Total Mean 0% SD 0% Total Mean 0% SD 0% #Skin: Squamous Cell Papilloma (2%)(2%)1/50 1/50 **Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% Total 1/50 (2%) Mean 2% SD 0% ...... #Skin: **Squamous Cell Papilloma or Papilloma** 1/50 (2%)1/50 (2%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% Total 1/50 (2%) Mean 2% SD 0% .....

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Page: 255

Report Date: 06/05/2013

Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male		Female						
#Skin: Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma											
		1/50 (2%)				1/50 (2%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%			
#Skin: Squamous Cell Papilloma						1/50 (2%)					
Overall Incidence	Total	1/50 (2%)	Mean 2%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%			
#Skin: Sebaceous Gland: Adenoma											
		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
#Spinal Cord: Hemangiosarcoma											
-		0/50 (0%)				0/50 (0%)					
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%			
*Spleen: Hemangioma		0/40 (09/)				0/40 (09/)					
Overall Instidence	Tatal	0/49 (0%)	Mann 00/	CD 00/	Tatal	0/49 (0%)	Mana 00/	CD 00/			
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Page: 256

Report Date: 06/05/2013

SD 0%

Mean 4%

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

Male **Female** \*Spleen: Hemangiosarcoma 4/49 (8%)0/49 (0%)**Overall Incidence** Total 4/49 (8.16%) Mean 8.16% SD 0% Total 0/49 (0%) Mean 0% SD 0% \*Spleen: **Mast Cell Tumor Malignant** 0/49 (0%)0/49 (0%)**Overall Incidence** Total 0/49 (0%) Mean 0% SD 0% Total 0/49 (0%) Mean 0% SD 0% \*Spleen: **Plasma Cell Tumor Malignant** 0/49 (0%)0/49 (0%)**Overall Incidence** Total 0/49 (0%) Mean 0% SD 0% Total 0/49 (0%) Mean 0% SD 0% ..... #Stomach, Forestomach: **Squamous Cell Carcinoma** 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total Mean 0% SD 0% 0/50 (0%) #Stomach, Forestomach: Squamous Cell Carcinoma or Papilloma Squamous 3/50 (6%)2/50 (4%)**Overall Incidence** Total 3/50 (6%) Mean 6% SD 0% Total 2/50 (4%) Mean 4% SD 0% #Stomach, Forestomach: Squamous Cell Papilloma 3/50 (6%)2/50 (4%)

SD 0%

Total

2/50 (4%)

Total

3/50 (6%)

Mean 6%

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Page: 257

Mean 0%

SD 0%

Report Date: 06/05/2013

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

Male **Female** #Stomach, Glandular: Adenoma 0/50 (0%)0/50 (0%)0/50 (0%) **Overall Incidence** Total Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #Stomach, Glandular: Carcinoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% #Stomach, Glandular: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% Total 0/50 (0%) Mean 0% SD 0% ...... \*Testes: Adenoma 1/50 (2%)**Overall Incidence** Total 1/50 (2%) Mean 2% SD 0% \*Testes: Hemangioma 0/50 (0%)**Overall Incidence** Total 0/50 (0%) Mean 0% SD 0% \*Thymus: Neoplasm NOS 0/48 (0%)0/47 (0%)

SD 0%

0/47 (0%)

Total

Total

0/48 (0%)

Mean 0%

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Page: 258

Report Date: 06/05/2013

Vehicle: ACETONE

Length of Study: CHRONIC

			Male			Female			
*Thymus: Thymoma Benign		0/48 (0%)				0/47 (0%)			
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%	
*Thymus: Thymoma Malignant		0/48 (0%)				1/47 (2%)			
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	1/47 (2.13%)	Mean 2.13%	SD 0%	
*Thymus: Thymoma: Benign, Malignar		0/48 (0%)				1/47 (2%)			
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	1/47 (2.13%)	Mean 2.13%	SD 0%	
*Thyroid Gland: C-Cell: Carcinoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%) 0/49 (0%)	Mean 0%	SD 0%	
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		0/50 (0%)				0/49 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
*Thyroid Gland: Follicular Cell Adenoma		0/50 (0%)				0/49 (0%)			
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 259

				Male				Female		
*Thyroid Gland: Follicular Cell: Carcinoma										
		0/50	(0%)				0/49 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma										
		0/50	(0%)				0/49 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%	
#Tissue NOS: Fibrosarcoma										
O	T-(-1	0/50	(0%)	M 00/	OD 00/	T-1-1	1/50 (2%)	Maran 00/	OD 00/	
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	1/50 (2%)	Mean 2%	SD 0%	
#Tissue NOS: Hemangiosarcoma		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)	(070)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Tissue NOS: Plasma Cell Tumor Malignan	t									
•		0/50	(0%)				0/50 (0%)			
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	
#Tissue NOS: Sarcoma		0.45-	(004)				(00)			
		0/50	(0%)				0/50 (0%)		05 00/	
Overall Incidence	Total	0/50 (0%)		Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 260 Report Date: 06/05/2013

Species: MICE Strain: B6C3F1 Route: SKIN

Vehicle: ACETONE

Length of Study: CHRONIC

			Male				Female	
#Tongue: Fibroma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma	or Papilloma					0/50 /00/		
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Papilloma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
#Tooth: Odontoma Overall Incidence	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%
#Urethra: Hemangiosarcoma		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangiosarcoma		0/47 (0%)				0/48 (0%)		
Overall Incidence	Total	0/47 (0%)	Mean 0%	SD 0%	Total	0/48 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 261

			Male				Female		
*Urinary Bladder: Plasma Cell Tumor Mali	ignant								
Overall Incidence	Total	0/47 (0%) 0/47 (0%)	Mean 0%	SD 0%	Total	0/48 (0%) 0/48 (0%)	Mean 0%	SD 0%	
#Uterus: Adenoma			•••••						
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Carcinoma									
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Hemangiosarcoma									
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Leiomyoma			•••••						
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Leiomyosarcoma									
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 262

			Male			Female			
#Uterus: Polyp Stromal						0/50 (0%)			
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Sarcoma						4/50 (00)			
Overall Incidence					Total	1/50 (2%) 1/50 (2%)	Mean 2%	SD 0%	
#Uterus: Sarcoma Stromal						0/50 (0%)			
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%	
#Uterus: Sarcoma Stromal or Polyp Strom						0/50 (0%)			
Overall Incidence					Total	0/50 (0%)	Mean 0%	SD 0%	
#Vagina: Liposarcoma									
Overall Incidence					Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	
#Zymbal's Gland: Carcinoma	0.11	-0 (00()				0/50 (00/)			
Overall Incidence Tot	0/5 al 0/50	(0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Report Date: 06/05/2013

Page: 263

			Male	Female				
#Zymbal's Gland: Carcinoma or Adenoma								
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Page: 264

Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

# **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Southern Research Institute	059500306	04/26/04	729	50(1)	34(694)	54.6	Methyl trans-styryl ketone
Battelle Columbus Laboratory	059903204	09/21/04	729	50(1)	37(698)	56.4	Pyrogallol
					Female		
Southern Research Institute	059500306	04/26/04	731	50(1)	37(709)	64.6	Methyl trans-styryl ketone
Battelle Columbus Laboratory	059903204	09/20/04	729	50(1)	33(675)	69.3	Pyrogallol

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 265

Report Date: 06/05/2013

Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

			Male			Female			
#All Organs: Benign Tumors									
		37/50 (74%)	42/50 (84%)			33/50 (66%)	34/50 (68%)		
verall Incidence	Total	79/100 (79%)	Mean 79%	SD 7.07%	Total	67/100 (67%)	Mean 67%	SD 1.41%	
All Organs: Malignant Tumors									
		37/50 (74%)	33/50 (66%)			42/50 (84%)	34/50 (68%)		
verall Incidence	Total	70/100 (70%)	Mean 70%	SD 5.66%	Total	76/100 (76%)	Mean 76%	SD 11.31%	
All Organs: Malignant and Benign To									
		49/50 (98%)	47/50 (94%)			48/50 (96%)	42/50 (84%)		
verall Incidence	Total	96/100 (96%)	Mean 96%	SD 2.83%	Total	90/100 (90%)	Mean 90%	SD 8.49%	
All Organs: Hemangioma		1/50 (2%)	1/50 (2%)			0/50 (0%)	1/50 (2%)		
verall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%	
All Organs: Hemangiosarcoma									
_		6/50 (12%)	5/50 (10%)			5/50 (10%)	6/50 (12%)		
verall Incidence	Total	11/100 (11%)	Mean 11%	SD 1.41%	Total	11/100 (11%)	Mean 11%	SD 1.41%	
All Organs: Hemangiosarcoma or He	emangioma	7/50 (4.40)	0/50 /4000			E/E0 (400()	7/50 (4.40)		
		7/50 (14%)	6/50 (12%)	05 4 4404		5/50 (10%)	7/50 (14%)	05	
verall Incidence	Total	13/100 (13%)	Mean 13%	SD 1.41%	Total	12/100 (12%)	Mean 12%	SD 2.83%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 266 Report Date: 06/05/2013

			Male			Female			
#All Organs: Histiocytic Sarcoma									
		0/50 (0%)	1/50 (2%)			1/50 (2%)	0/50 (0%)		
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%	
#All Organs: Malignant Lymphoma: Hi	stiocytic, Lym	phocytic, Mixed, NOS, or	Undifferentiated Cel	I Туре					
		4/50 (8%)	2/50 (4%)			20/50 (40%)	13/50 (26%)		
Overall Incidence	Total	6/100 (6%)	Mean 6%	SD 2.83%	Total	33/100 (33%)	Mean 33%	SD 9.9%	
#All Organs: Mesothelioma: Benign		0(50 (00))	0/50 (00/)			0/50 (00/)	0(50 (00))		
	<b>+</b>	0/50 (0%)	0/50 (0%)	<b>OD</b> 00/	<b>+</b>	0/50 (0%)	0/50 (0%)	OD 00/	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#All Organs: Mesothelioma: Benign, M	alignant, NOS		0/50 (09/)			0/50 (00/)	0/50 (09/)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#All Organs: Mesothelioma: Malignant									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#All Organs: Osteoma						- 1 1			
		0/50 (0%)	0/50 (0%)	05.00/		0/50 (0%)	0/50 (0%)	05.00/	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 267

			Male			Female				
#All Organs: Osteosarcoma										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#All Organs: Osteosarcoma or Osteoma										
		0/50 (0%)	0/50 (0%)	25. 20/		0/50 (0%)	0/50 (0%)	00.004		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
*Adrenal Cortex: Adenoma										
		6/50 (12%)	9/50 (18%)			0/50 (0%)	1/50 (2%)			
Overall Incidence	Total	15/100 (15%)	Mean 15%	SD 4.24%	Total	1/100 (1%)	Mean 1%	SD 1.41%		
*Adrenal Cortex: Plasma Cell Tumor Malignar	nt	0/50 (00/)	0/50 (00/)			0(50 (00())	0/50 /00/)			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
*Adrenal Medulla: Pheochromocytoma Benign										
		0/49 (0%)	0/50 (0%)			0/50 (0%)	2/50 (4%)			
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 2.83%		
*Adrenal Medulla: Pheochromocytoma Maligna	ant									
		0/49 (0%)	0/50 (0%)	25. 20/		1/50 (2%)	0/50 (0%)	00 4 4404		
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 268 Report Date: 06/05/2013

			Male				Female	
*Adrenal Medulla: Pheochromocytoma: Ben	ign, Complex,	<b>Malignant, NOS</b> 0/49 (0%)	0/50 (0%)			1/50 (2%)	2/50 (4%)	
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 1.41%
#Blood Vessel: Hemangioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Bone Marrow: Hemangioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Bone Marrow: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			1/50 (2%)	3/50 (6%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	4/100 (4%)	Mean 4%	SD 2.83%
*Bone Marrow: Mast Cell Tumor Malignar	nt							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Bone Marrow: Plasma Cell Tumor Maligr	nant	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 269

			Male		0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD  0/50 (0%) 3/50 (6%) Total 3/100 (3%) Mean 3% SD 4  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD			
*Bone Marrow: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` '	` ,	SD 0%
#Bone: Fibroma								•••••
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` '	` '	SD 0%
#Bone: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (00()	2/52 (201)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` '	` ,	SD 4.24%
#Bone: Osteoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		0/100 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` '	` '	SD 0%
#Bone: Osteosarcoma or Osteoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 270

			Male Female				0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD (0%)  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD (0%)  Total 0/100 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD (0%)  Total 0/100 (0%) Mean 0% SD (0%)  Total 0/100 (0%) Mean 0% SD (0%)  O/50 (0%) 0/50 (0%)  O/50 (0%) 0/50 (0%)		
#Bone: Sarcoma									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		, ,		SD 0%	
*Brain: Granular Cell Tumor Benig	gn								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
*Brain: Meningioma Benign		0/50 (00/)	0/50 /00/)			0/50 (00/)	0/50 (00)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` ,	` '	SD 00/	
Overall incidence	Total	0/100 (0%)	iviean 0%	3D 0%	rotai	0/100 (0%)		טט עא U%	
*Brain: Meningioma Malignant		0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		0/100 (0%)	Mean 0%	SD 0%	
*Brain: Meningioma: Benign, Mali									
	_	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
*Brain: Oligodendroglioma Maligr	nant								
		0/50 (0%)	0/50 (0%)			` ,	` '		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Report Date: 06/05/2013

Page: 271

			Male				Female	
*Brain: Oligodendroglioma, Glion	na, or Astrocy	rtoma						
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangioma		- (a)					(201)	
	<b>-</b>	0/50 (0%)	1/50 (2%)	00 4 440/	<b>-</b>	0/48 (0%)	0/49 (0%)	OD 00/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/97 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangiosarcoma								
		0/50 (0%)	1/50 (2%)	00 4 4404		0/48 (0%)	0/49 (0%)	05 00/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/97 (0%)	Mean 0%	SD 0%
#Coagulating Gland: Granular Cell Tumor								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Coagulating Gland: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 272

			Male Female				O/50 (0%) O/50 (0%) Total O/100 (0%) Mean 0% SD 0  O/50 (0%) O/50 (0%) Total O/100 (0%) Mean 0% SD 0  4/50 (8%) 1/50 (2%) Total 5/100 (5%) Mean 5% SD 4.2  O/50 (0%) 2/50 (4%) Total 2/100 (2%) Mean 2% SD 2.8  4/50 (8%) 3/50 (6%) Total 7/100 (7%) Mean 7% SD 1.4		
#Esophagus: Squamous Cell Carcinoma	ı								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` '	` '	SD 0%	
		0/100 (0/0)		30 0%					
#Eye: Melanoma Malignant									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` '	` ,	SD 0%	
#Harderian Gland: Adenoma									
Overall Incidence	Total	2/50 (4%) 8/100 (8%)	6/50 (12%) Mean 8%	SD 5.66%	Total	` ,	` ,	SD 4.24%	
#Harderian Gland: Carcinoma									
Overall Incidence	Total	1/50 (2%) 3/100 (3%)	2/50 (4%) Mean 3%	SD 1.41%		2/100 (2%)	Mean 2%	SD 2.83%	
#Harderian Gland: Carcinoma or Adenoma									
		3/50 (6%)	8/50 (16%)			` '	` '		
Overall Incidence	Total	11/100 (11%)	Mean 11%	SD 7.07%	Total	7/100 (7%)	Mean 7%	SD 1.41%	
*Heart: Hemangiosarcoma									
Occupation of the second	T-1-1	1/50 (2%)	0/50 (0%)	00 4 440/	Tatal	0/50 (0%)	0/50 (0%)	00.00/	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 273

Report Date: 06/05/2013

Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female		
#Intestine Large: Cecum: Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Carcinoma		4/50 (004)	0/50 (00)			0/50 (004)	2/52 (22/)	
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Large: Cecum: Carcinoma or Adenoma								
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Large: Cecum: Leiomyoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Leiomyosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Large: Colon/Rect Leiomyosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 274

			Male		1/50 (2%) 0/50 (0%)  Total 1/100 (1%) Mean 1% S  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0%  Total 0/100 (0%) Mean 0%  Total 0/100 (0%) 0/50 (0%)  Mean 0%			
#Intestine Small: Duodenum: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Carcinoma								
		0/50 (0%)	0/50 (0%)			` ,	, ,	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Intestine Small: Duodenum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)			` '	, ,	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		, ,		SD 0%
#Intestine Small: Duodenum: Polyp Adenomatous		0/50 (00)	0/50 (00()			0(50 (00))	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	, ,	` '	SD 0%
		` '				` ,		
#Intestine Small: Ileum: Adenoma								
		0/50 (0%)	0/50 (0%)			` '	` ,	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 275

			Male		0/50 (0%) 1/50 (2%) Total 1/100 (1%) Mean 1%  1/50 (2%) 0/50 (0%) Total 1/100 (1%) Mean 1%  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%			
#Intestine Small: Ileum: Polyp Adenomatous								
		0/50 (0%)	0/50 (0%)			` '	(/	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Adenoma								
		1/50 (2%)	0/50 (0%)			` '	` ,	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Carcinoma								
		1/50 (2%)	1/50 (2%)			` '	` ,	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Intestine Small: Jejunum: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			` '	` ,	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%		, ,		SD 1.41%
#Intestine Small: Jejunum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Page: 276

Report Date: 06/05/2013

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups
Route: SKIN

Species: MICE Strain: B6C3F1

Vehicle: ETHANOL

Length of Study: CHRONIC

			Male				Female	
#Intestine Small: Site Unsp Carcinoma	ecified:				0/50 (0%)			
		1/50 (2%)	1/50 (2%)			` ,	1/50 (2%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 0%
#Intestine Small: Site Unsp Carcinoma or Adenoma	ecified:							
		2/50 (4%)	1/50 (2%)			( ,	1/50 (2%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 0%
#Intestine Small: Site Unsp Hemangiosarcoma	ecified:							
		0/50 (0%)	0/50 (0%)			` ,	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Intestine Small: Site Unsp Leiomyosarcoma	ecified:							
		0/50 (0%)	0/50 (0%)			` '	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp Polyp Adenomatous								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma	•••••							
		2/50 (4%)	1/50 (2%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 277

			Male				Female	
*Islets, Pancreatic: Carcinoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma								
		2/50 (4%)	2/50 (4%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Kidney: Pelvis and Transition Carcinoma	onal Epitheliu	ım:						
		0/48 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Kidney: Pelvis and Transitio Carcinoma or Adenoma		ım:						
Overall Incidence	Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
		·····				······		
*Kidney: Renal Tubule: Adenoma								
		1/48 (2%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	1/98 (1.02%)	Mean 1.04%	SD 1.47%	Total	0/99 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma	•••••							
		0/48 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 278

Report Date: 06/05/2013

Route: SKIN

Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Kidney: Renal Tubule: Carcinoma or Adenoma								
Overall Incidence	Total	1/48 (2%) 1/98 (1.02%)	0/50 (0%) Mean 1.04%	SD 1.47%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangioma		2/12 (22/)	0.770			2(12 (22)	(00)	
Overall Incidence	Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangiosarcoma	•••••		•••••					
Overall Incidence	Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 1/99 (1.01%)	1/50 (2%) Mean 1%	SD 1.41%
*Kidney: Renal Tubule: Plasma Cell Tumor Malign		0/48 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Sarcoma								
Overall Incidence	Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/49 (2%) 1/99 (1.01%)	0/50 (0%) Mean 1.02%	SD 1.44%
*Liver: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 279

		Male Female					1/50 (2%) 1/50 (2%) otal 2/100 (2%) Mean 2% SD 0%  0/50 (0%) 1/50 (2%) otal 1/100 (1%) Mean 1% SD 1.41%  30/50 (60%) 30/50 (60%) otal 60/100 (60%) Mean 60% SD 0%  23/50 (46%) 17/50 (34%) otal 40/100 (40%) Mean 40% SD 8.49%		
*Liver: Hemangiosarcoma									
		4/50 (8%)	3/50 (6%)			1/50 (2%)	1/50 (2%)		
Overall Incidence	Total	7/100 (7%)	Mean 7%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 0%	
*Liver: Hepatoblastoma									
		1/50 (2%)	4/50 (8%)			` ,	` ,		
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 4.24%	Total	1/100 (1%)	Mean 1%	SD 1.41%	
*Liver: Hepatocellular Adenoma		04/50 (000()	00/50 /700/)			00/50 (000/)	00(50 (000))		
	<b>.</b>	31/50 (62%)	39/50 (78%)	00 44 040/	<b>.</b>	` ,	` ,	00.00/	
Overall Incidence	Total	70/100 (70%)	Mean 70%	SD 11.31%	Total	60/100 (60%)	Mean 60%	SD 0%	
*Liver: Hepatocellular Carcinoma									
		28/50 (56%)	20/50 (40%)			` ,	` ,		
Overall Incidence	Total	48/100 (48%)	Mean 48%	SD 11.31%	Total	40/100 (40%)	Mean 40%	SD 8.49%	
*Liver: Hepatocellular Carcinoma	or Hepatobl	astoma							
·	·	29/50 (58%)	21/50 (42%)			23/50 (46%)	18/50 (36%)		
Overall Incidence	Total	50/100 (50%)	Mean 50%	SD 11.31%	Total	41/100 (41%)	Mean 41%	SD 7.07%	
*Liver: Hepatocellular Carcinoma o		ellular Adenoma				00/50 /700/)	05/50 /700/\		
O	T-1-1	45/50 (90%)	43/50 (86%)	OD 0.000/	T-1-1	` ,	` ,	OD 4 040/	
Overall Incidence	Total	88/100 (88%)	Mean 88%	SD 2.83%	Total	73/100 (73%)	Mean 73%	SD 4.24%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 280

			Male				Female		
*Liver: Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma  45/50 (90%) 43/50 (86%)  Overall Incidence  Total 88/100 (88%) Mean 88% SD 2.83% Total 73/100 (73%) Mean 73% SD 4.24%									
*Liver:		00,100 (00,0)		22 2.30%		7.67.100 (1.67.6)		05 1.27%	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
*Liver: Hepatocholangioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
*Liver: Ito Cell Tumor Benign		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
*Liver: Mast Cell Tumor Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
*Liver: Plasma Cell Tumor Maligna	ant								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 281

			Male			Female       0/50 (0%) 0/100 (0%)     0/50 (0%) 0/50 (0%)       1/50 (2%) 2/50 (4%)     3/100 (3%)     Mean 3%     SD 1.41%       3/50 (6%) 2/50 (4%)       5/100 (5%)     Mean 5%     SD 1.41%       4/50 (8%) 4/50 (8%)       8/100 (8%)     Mean 8%     SD 0%       1/50 (2%) 0/50 (0%)       1/100 (1%)     Mean 1%     SD 1.41%		
*Liver: Sarcoma								
		0/50 (0%)	0/50 (0%)			` ,	(/	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Lung: Alveolar/Bronchiolar A	denoma							
		8/50 (16%)	12/50 (24%)			1/50 (2%)	2/50 (4%)	
Overall Incidence	Total	20/100 (20%)	Mean 20%	SD 5.66%	Total	` '		SD 1.41%
Lung: Alveolar/Bronchiolar C								
		7/50 (14%)	4/50 (8%)			3/50 (6%)	2/50 (4%)	
Overall Incidence	Total	11/100 (11%)	Mean 11%	SD 4.24%	Total	, ,		
Lung:		veolar/Bronchiolar Adenor 14/50 (28%)						
Overall Incidence	Total	29/100 (29%)	Mean 29%	SD 1.41%	Total	8/100 (8%)	` ,	SD 0%
Lung: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
Lung: Plasma Cell Tumor Mal	lignant							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 282

		Male				Female				
#Lymph Node: Plasma Cell Tumor Malignant										
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
<b>-</b>	` '	, ,	00.00/	<b>+</b>	` '	` '	OD 00/			
ı otal	0/100 (0%)	Mean 0%	SD 0%	l otal	0/100 (0%)	Mean 0%	SD 0%			
nt	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
nant										
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
nt	0/50 (09/)	0/50 (0%)			0/50 (09/)	0/50 (09/)				
Total	` '	` ,	SD 0%	Total	` '	` '	SD 0%			
	Total  Total  Total  Total  Total  Total	0/50 (0%) Total 0/100 (0%)  0/50 (0%) Total 0/100 (0%)  Total 0/50 (0%) Total 0/100 (0%)  Total 0/50 (0%)  Total 0/100 (0%)  Total 0/100 (0%)  Total 0/50 (0%)  Total 0/50 (0%)  Total 0/50 (0%)	Total 0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0%  10t  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0%  10t  10t  10t  10t  10t  10t  10t  1	Total 0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD 0%     0/50 (0%) 0/50 (0%)   Total 0/100 (0%) Mean 0% SD 0%    Total 0/100 (0%) Mean 0% SD 0%	Total 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total  1t  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total  1t  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total  1t  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total	Total 0/50 (0%) 0/50 (0%) SD 0% Total 0/100 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)	Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) 0/50 (0%) Mean 0% SD 0%  Total 0/100 (0%) 0/50 (0%) Mean 0%  Total 0/100 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%  Total 0/100 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Report D

Report Date: 06/05/2013

Page: 283

			Male				Female	
#Lymph Node, Mesenteric: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
						0/100 (0 /8)		
#Lymph Node, Mesenteric: Plasma Cell Tumor Malign	ant							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Mammary Gland: Adenoma		0(50 (00))	0/50 (00/)			0(50 (00())	0/50 (00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Mammary Gland: Carcinoma		0/50 (0%)	0/50 (0%)			2/50 (4%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 2.83%
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			2/50 (4%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 2.83%
#Mammary Gland: Fibroadenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 284

			Male				Female		
#Mammary Gland: Fibroma, Fibroadenoma or Adenoma									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Mammary Gland: Fibroma, Fibroadenom	a, Carcinoma, or	Adenoma							
		0/50 (0%)	0/50 (0%)			2/50 (4%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 2.83%	
#Mesentery: Hemangioma		0/50 (00/)	0/50 (00)			0/50 (00/)	0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
					10tai	0/100 (0%)			
#Mesentery: Hemangiosarcoma							. ()		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	
Overall incidence	ı olal	0/100 (0%)			Total	0/100 (0%)	wean 0%	3D 0%	
#Mesentery: Lipoma									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Mesentery: Sarcoma		0/50 (051)	4/50 (05:)			0/50 (00)	0/50 /00/		
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
		1/100 (1%)			Total	` '			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Page: 285

Report Date: 06/05/2013

Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1 Length of Study: CHRONIC Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

			Male				Female	
*Nose: Adenoma		0(50 (00))	2/52 (224)			0/50 (00)	0/50 (00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Nose: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucos Papilloma Squamous o Overall Incidence	r Papilloma Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Oral Cavity (Oral Mucos	a, Tongue, Phar					0/100 (0%)	Mean 0%	SD 0%
Squamous Cell Carcino  Overall Incidence	oma Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Oral Cavity (Oral Mucos Squamous Cell Carcino		ynx, Tooth, Gingiva): Squamous, or Papilloma 0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Oral Mucosa: Squamous Cell Carcino	oma							

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 286

	Male		Female	
*Ovary: Choriocarcinoma		0/40 (00/)	2/52 (224)	
Overall Incidence	Tota	0/49 (0%) al 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Cystadenocarcinoma		0/49 (0%)	0/50 (0%)	
Overall Incidence	Tota	` '	Mean 0%	SD 0%
*Ovary: Cystadenoma		4/40 (20/)	2/50 (40/)	
Overall Incidence	Tota	1/49 (2%) al 3/99 (3.03%)	2/50 (4%) Mean 3.02%	SD 1.39%
*Ovary: Granulosa Cell Tumor Benign		0/49 (0%)	1/50 (2%)	
Overall Incidence	Tota	ıl 1/99 (1.01%)	Mean 1%	SD 1.41%
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS				
Overall Incidence	Tota		1/50 (2%) Mean 1%	SD 1.41%
*Ovary: Hemangioma				
Overall Incidence	Tota	` ,	1/50 (2%) Mean 1%	SD 1.41%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 287

	Male			Female	
*Ovary: Hemangiosarcoma			0/40 (00%)	4/50 (00())	
Overall Incidence		Total	0/49 (0%) 1/99 (1.01%)	1/50 (2%) Mean 1%	SD 1.41%
*Ovary: Luteoma					
Overall Incidence		Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Plasma Cell Tumor Malignant			0/40 (0%)	0/50 (09/)	
Overall Incidence		Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Sarcoma			0/49 (0%)	0/50 (0%)	
Overall Incidence		Total	0/99 (0%)	Mean 0%	SD 0%
*Ovary: Teratoma Benign					
Overall Incidence		Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Teratoma Malignant			0/40 (00/)	0/50 (09/)	
Overall Incidence		Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Page: 288

Mean 9.32%

SD 1.87%

SD 0%

Report Date: 06/05/2013

Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1

\*Ovary:

\*Ovary:

\*Pancreas: Carcinoma

\*Pancreas:

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Male **Female Tubulostromal Adenoma** 0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% Yolk Sac Carcinoma 0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% 0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% ..... Carcinoma or Adenoma 0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% \*Pituitary Gland: Pars Distalis or Unspecified Site: 0/49 (0%)0/50 (0%)5/47 (11%) 4/50 (8%)

Total

9/97 (9.28%)

\*Pituitary Gland: Pars Distalis or Unspecified Site:

Carcinoma

Adenoma

**Overall Incidence** 

0/49 (0%)0/50 (0%)0/47 (0%)0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% Mean 0% Total 0/97 (0%)

SD 0%

Mean 0%

\*: Denominator is number of animals with tissues examined microscopically

Total

0/99 (0%)

#: Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 289

			Male				Female	
*Pituitary Gland: Pars Dist Carcinoma or Adenoma		fied Site:						
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	5/47 (11%) 9/97 (9.28%)	4/50 (8%) Mean 9.32%	SD 1.87%
*Pituitary Gland: Pars Intel	rmedia:							
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/47 (0%) 0/97 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pituitary Gland: Pars Intel Carcinoma or Adenoma	rmedia:							
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/47 (0%) 0/97 (0%)	0/50 (0%) Mean 0%	SD 0%
*Salivary Glands: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Salivary Glands: Hemangiosarcoma		0/50 (00/)	0/50 /00/			0/50 /00/	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 290

			Male				Female	
Salivary Glands: Mast Cell Tumor Malignant								
•		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Salivary Glands: Myxoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Seminal Vesicle: Adenoma		0/50 (00)	0/50 (05.1)					
		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
Skeletal Muscle: Hemangiosarcoma								
		1/50 (2%)	0/50 (0%)			1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma or Rh	abdomyoma							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Page: 291

Report Date: 06/05/2013

Contract/Lab: All Laboratories

Species: MICE

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Strain: B6C3F1 Length of Study: CHRONIC Male **Female #Skeletal Muscle:** Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% #Skin: **Basal Cell Carcinoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% Total #Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% Total ...... #Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/100 (0%) Overall Incidence Total 0/100 (0%) Mean 0% SD 0% Total Mean 0% SD 0% #Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma 0/50 (0%)0/50 (0%)0/50 0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0%

1/50

2/100 (2%)

Total

(2%)

1/50

(2%)Mean 2%

SD 0%

Total

Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma

(2%)

2/100 (2%)

1/50

Mean 2%

(2%)

SD 0%

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 292

			Male				Female	
#Skin: Fibrosarcoma		1/50 (2%)	0/50 (0%)			1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 0%
#Skin: Fibrosarcoma, Sarcoma,	Myxosarcoma	, or Fibrous Histiocytoma						
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%
#Skin: Fibrous Histiocytoma		0/50 (00/)	4/50 /00/			0/50 (09/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Granular Cell Tumor Ben	ign	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Hemangioma								
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Hemangiosarcoma								
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 293

			Male				Female	
#Skin: Keratoacanthoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Lipoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Liposarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Mast Cell Tumor Benign						(70)	(201)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Skin: Mast Cell Tumor Malignant								
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Melanoma Benign								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 294

			Male				Female	
#Skin: Melanoma Malignant								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Neural Crest Tumor								
Neural Orest rumor		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin:								
Neurofibroma or Schw	annoma benign							
Occupation of the second	T-1-1	0/50 (0%)	0/50 (0%)	00.00/	T-1-1	0/50 (0%)	1/50 (2%)	00 4 440/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin:								
Neurofibrosarcoma or	Schwannoma (m		0/50 (00/)			1/50 (20/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Skin:								
Neurofibrosarcoma, Ne	eurofibroma, or S	Schwannoma (benign, ma 0/50 (0%)	lignant or NOS) 0/50 (0%)			1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	0/30 (0%) Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 0%
#Skin: Osteosarcoma								
	<b>-</b>	0/50 (0%)	0/50 (0%)	00.00/	<b>+</b>	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 295

			Male				Female	
#Skin: Sarcoma		0/50 /00//	0/50 (00/)			0/50 /00/	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Schwannoma Benign		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Schwannoma Malignant								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Skin: Squamous Cell Carcinoma or Carcinoma	, Basal Cell C	Carcinoma, Basosquamou	us Tumor (malignant o	or NOS),				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma of	or Papilloma							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 296

			Male				Female	
#Skin: Squamous Cell Papilloma	, Papilloma, S	•	or Keratoacanthoma	ı				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma	, Papilloma, o		0.750			0.50	(201)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Spinal Cord: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
*Spleen: Hemangioma		0/49 (00/)	0/50 (0%)			0/40 (09/)	0/50 (0%)	
Overall Incidence	Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 297

			Male				Female	
*Spleen: Hemangiosarcoma								
Overell besidence	Tatal	3/48 (6%)	1/50 (2%)	CD 2.040/	Tatal	2/49 (4%)	1/50 (2%)	CD 4.470/
Overall Incidence	Total	4/98 (4.08%)	Mean 4.12%	SD 3.01%	Total	3/99 (3.03%)	Mean 3.04%	SD 1.47%
Spleen: Mast Cell Tumor Malignant								
		0/48 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
Spleen: Plasma Cell Tumor Malignar								
		0/48 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma c	or Papillom		4/50 (00)			4/50 (00/)	4/50 (00/)	
Overall Incidence	Total	4/50 (8%) 5/100 (5%)	1/50 (2%) Mean 5%	SD 4.24%	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%
weran incluence	ı uldı	J/100 (5%)	IVIEAII 5%	3D 4.24%	Total	۷/۱۵۵ (۲%)	iviean 2%	JD U%
Stomach, Forestomach: Squamous Cell Papilloma								
		3/50 (6%)	1/50 (2%)		_	1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 2.83%	Total	2/100 (2%)	Mean 2%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 298

			Male				Female	
#Stomach, Glandular: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma	•••••	0/50 (00/)	0/50 (00/)			0/50 (001)	0 (50 (00))	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma or Adenoma							(201)	
O	T-1-1	0/50 (0%)	0/50 (0%)	00.00/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Testes: Adenoma			- ()					
O ! . !	T-1-1	0/50 (0%)	0/50 (0%)	00.00/				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
*Testes: Hemangioma								
_		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
*Thymus: Neoplasm NOS								
		0/44 (0%)	0/48 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/92 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 299

			Male				Female	
*Thymus: Thymoma Benign								
		0/44 (0%)	0/48 (0%)			0/50 (0%)	0/50 (0%)	00.004
Overall Incidence	Total	0/92 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant								
		0/44 (0%)	0/48 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/92 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Maligna	ant, NOS	0/44 (0%)	0/48 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/92 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma								
Occupation of James	Tatal	0/50 (0%)	0/50 (0%)	OD 00/	Tatal	0/49 (0%)	0/50 (0%)	00.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Ce Adenoma	II:							
	<b>.</b>	1/50 (2%)	0/50 (0%)	05 4 440/	<b>-</b>	0/49 (0%)	0/50 (0%)	00.004
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/99 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL **Page:** 300

			Male			Female			
*Thyroid Gland: Follicular Cell: Carcinoma									
		0/50 (0%)	0/50 (0%)			1/49 (2%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma									
		1/50 (2%)	0/50 (0%)			1/49 (2%)	0/50 (0%)		
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	
#Tissue NOS: Fibrosarcoma									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Tissue NOS: Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)			1/50 (2%)	1/50 (2%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 0%	
#Tissue NOS: Plasma Cell Tumor Malignan	t								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Tissue NOS: Sarcoma									
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 301

0/50 I 0/100 (0%)	(0%) 0/50 (0%			,		
	(0%) 0/50 (0%			·		
ı	` '	,		0/50 (0%)	0/50 (0%)	25 201
2. 122 (070)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
illoma Squamous						
0/50	(0%) 0/50 (0%	(a)		0/50 (0%)	0/50 (0%)	
0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
0/50	(0%) 0/50 (0%)	2)		0/50 (0%)	0/50 (0%)	
	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
0/50	(00)	Α		0/50 (00/)	0/50 (00/)	
	(0%) 1/50 (2%) Mean 1%	sD 1.41%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
	` '	,		0/50 (0%)	0/50 (0%)	
d 0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
0/40	(00)	Δ		0/40 /00/	0/50 (00/)	
	` '	,	Total	` '	` '	SD 0%
	0/50 0/100 (0%)  0/50 0/100 (0%)  0/50 1/100 (1%)  0/50 1/100 (1%)	0/50 (0%) 0/50 (0%)  0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%)  1 0/100 (0%) Mean 0%  0/50 (0%) 1/50 (2%  1 1/100 (1%) Mean 1%  0/50 (0%) 0/50 (0%)  1 0/100 (0%) Mean 0%	0/50 (0%) 0/50 (0%)  Mean 0% SD 0%  0/50 (0%) 0/50 (0%)  0/100 (0%) Mean 0% SD 0%  0/50 (0%) 1/50 (2%)  1/100 (1%) Mean 1% SD 1.41%  0/50 (0%) 0/50 (0%)  0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)  Mean 0% SD 0% Total  0/50 (0%) 0/50 (0%)  Mean 0% SD 0% Total  0/50 (0%) Mean 0% SD 0% Total  0/50 (0%) 1/50 (2%)  1/100 (1%) Mean 1% SD 1.41% Total  0/50 (0%) 0/50 (0%)  0/50 (0%) SD 0% Total	0/50 (0%) 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  0/50 (0%) 0/50 (0%) 0/100 (0%) 0/50 (0%) 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  0/50 (0%) 1/50 (2%) 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%)  0/50 (0%) 0/50 (0%) 1/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  0/50 (0%) 0/50 (0%) 1/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  0/49 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  0/50 (0%) Mean 0%  0/50 (0%) Mean 0%  0/50 (0%) Mean 0%  0/50 (0%) Mean 0%  Total 0/100 (0%) 0/50 (0%)  0/50 (0%) Mean 0%  Total 0/100 (0%) Mean 0%  0/50 (0%) Mean 0%  1/100 (1%) Mean 1%  SD 1.41%  Total 0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%)  1/100 (1%) Mean 1%  SD 1.41%  Total 0/100 (0%) Mean 0%  0/50 (0%) Mean 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

trol Animal Groups

Page: 302

Report Date: 06/05/2013

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

			Male		Female			
*Urinary Bladder: Plasma Cell Tumor Malig								
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Adenoma				•••••	•••••	•••••	•••••	
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Carcinoma								
Overall Incidence					Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%
#Uterus: Hemangiosarcoma								
Overall Incidence					Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Uterus: Leiomyoma				•••••		•••••	•••••	
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Leiomyosarcoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 303

		Male				Female	
#Uterus: Polyp Stromal							
Overall Incidence				Total	1/50 (2%) 4/100 (4%)	3/50 (6%) Mean 4%	SD 2.83%
#Uterus: Sarcoma							
Overall Incidence				Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Sarcoma Stromal							
Overall Incidence				Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Sarcoma Stromal or Polyp Stromal					4/50 (00/)	0/50 (00/)	
Overall Incidence				Total	1/50 (2%) 4/100 (4%)	3/50 (6%) Mean 4%	SD 2.83%
#Vagina: Liposarcoma							
Overall Incidence				Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Zymbal's Gland: Carcinoma							
Overall Incidence Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Report Date: 06/05/2013

Page: 304

nicle: ETHANOL		

	Male					Female				
#Zymbal's Gland: Carcinoma or Adenoma										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied